MAIL TO:

STATE OF UTAH
DIVISION OF PURCHASING
3150 STATE OFFICE BUILDING, STATE CAPITOL
P.O. BOX 141061
SALT LAKE CITY, UTAH 84114-1061
TELEPHONE (801) 538-3026
http://purchasing.utah.gov

Request for Proposal

Solicitation Number: **JG6003**

Due Date: **07/13/05 at 3:00 P.M.**

Date Sent: June 28, 2005

Agency Contract

Goods and services to be purchased: **NEWBORN SCREENING LABORATORY INFORMATION MANAGEMENT SYSTEM FOR THE DEPARTMENT OF HEALTH**

Please complete

Company Name		Federal Tax Identification Number	
Ordering Address	City	State	Zip Code
Remittance Address (if different from ordering address)	City	State	Zip Code
Type ☐ Corporation ☐ Partnership ☐ Proprietorship ☐ Government	Company Contact Person		
Telephone Number (include area code)	Fax Number (include area code)		
Company's Internet Web Address	Email Address		
Discount Terms (for bid purposes, bid discounts less than 30 days will not be considered)	Days Required for Delivery After Receipt of Order (see attached for any required minimums)		

The following documents are included in this solicitation: Solicitation forms, instructions and general provisions, and specifications. Please review all documents carefully before completing.

The undersigned certifies that the goods or services offered are produced, mined, grown, manufactured, or performed in Utah. Yes_____ No_____. If no, enter where produced, etc._____

Offeror's Authorized Representative's Signature	Date
Type or Print Name	Position or Title

STATE OF UTAH
DIVISION OF PURCHASING

Request for Proposal

Solicitation Number: JG6003

Due Date: 07/13/05

Vendor Name:

NEWBORN SCREENING LABORATORY INFORMATION MANAGEMENT SYSTEM PER ATTACHED SPECIFICATIONS.

WITH PURCHASING QUESTIONS OR FOR CLARIFICATION PLEASE CONTACT JARED GARDNER AT 801-538-3342.
****
REFERENCE RX: 270 63000000001

Ship To: DEPT. OF HEALTH/CANNON HEALTH BUILDING
288 NORTH 1460 WEST
SALT LAKE CITY, UTAH 84116

REQUEST FOR PROPOSAL - INSTRUCTIONS AND GENERAL PROVISIONS

1. PROPOSAL PREPARATION: (a) All prices and notations must be in ink or typewritten. (b) Price each item separately. Unit price shall be shown and a total price shall be entered for each item bid. (c) Unit price will govern, if there is an error in the extension. (d) Delivery time of services and products as proposed is critical and must be adhered to. (e) All products are to be of new, unused condition, unless otherwise requested in this solicitation. (f) Incomplete proposals may be rejected. (g) This proposal may not be withdrawn for a period of 60 days from the due date. (h) Where applicable, all proposals must include complete manufacturer's descriptive literature. (i) By signing the proposal the offeror certifies that all of the information provided is accurate, that they are willing and able to furnish the item(s) specified, and that prices offered are correct.

2. SUBMITTING THE PROPOSAL: (a) The proposal must be signed in ink, sealed, and delivered to the DIVISION OF PURCHASING (DIVISION), 3150 State Office Building, Capitol Hill, Salt Lake City, UT 84114-1061. **The "Solicitation Number" and "Due Date" must appear on the outside of the envelope.** (b) Proposals, modifications, or corrections received after the closing time on the "Due Date" will be considered late and handled in accordance with the Utah Procurement Rules, section 3-209. (c) **Your proposal will be considered only if it is submitted on the forms provided by the state. Facsimile transmission of proposals to DIVISION will not be considered.** (d) All prices quoted must be both F.O.B. Origin per paragraph 1.(c) and F.O.B. Destination. Additional charges including but not limited to delivery, drayage, express, parcel post, packing, cartage, insurance, license fees, permits, costs of bonds, or for any other purpose must be included in the proposal for consideration and approval by the Division of Purchasing & General Services (DIVISION). Upon award of the contract, the shipping terms will be F.O.B. Destination with all transportation and handling charges paid by the Contractor, unless otherwise specified by the DIVISION. No charge for delivery, drayage, express, parcel post, packing, cartage, insurance, license fees, permits, costs of bonds, or for any other purpose will be paid by the state unless specifically included in the proposal and accepted by DIVISION. (e) By signing the proposal the offeror certifies that all of the information provided is accurate and that he/she offers to furnish materials/services for purchase in strict accordance with the requirements of this proposal including all terms and conditions.

3. SOLICITATION AMENDMENTS: All changes to this solicitation will be made through written addendum only. Bidders are cautioned not to consider verbal modifications.

4. PROPRIETARY INFORMATION: Suppliers are required to mark any specific information contained in their bid which is not to be disclosed to the public or used for purposes other than the evaluation of the bid. Each request for non-disclosure must be accompanied by a specific justification explaining why the information is to be protected. Pricing and service elements of any proposal will not be considered proprietary. All material becomes the property of the state and may be returned only at the state's option. Proposals submitted may be reviewed and evaluated by any persons at the discretion of the state.

5. BEST AND FINAL OFFERS: Discussions may be conducted with offerors who submit proposals determined to be reasonably susceptible of being selected for award for the purpose of assuring full understanding of, and responsiveness to, solicitation requirements. Prior to award, these offerors may be asked to submit best and final offers. In conducting discussions, there shall be no disclosure of any information derived from proposals submitted by a competing offeror.

6. SAMPLES: Samples, brochures, etc., when required, must be furnished free of expense to the state and if not destroyed by tests may, upon request made at the time the sample is furnished, be returned at the offeror's expense.

7. DIVISION APPROVAL: Contracts written with the State of Utah, as a result of this proposal, will not be legally binding without the written approval of the Director of the DIVISION.

8. AWARD OF CONTRACT: (a) The contract will be awarded with reasonable promptness, by written notice, to the responsible offeror whose proposal is determined to be the most advantageous to the state, taking into consideration price and evaluation factors set forth in the RFP. No other factors or criteria will be used in the evaluation. The contract file shall contain the basis on which the award is made. Refer to Utah Code Annotated 65-56-21. (b) The DIVISION can reject any and all proposals. And it can waive any informality, or technicality in any proposal received, if the DIVISION believes it would serve the best interests of the state. (c) Before, or after, the award of a contract the DIVISION has the right to inspect the offeror's premises and all business records to determine the offeror's ability to meet contract requirements. (d) The DIVISION will open proposals publicly, identifying only the names of the offerors. Proposals and modifications shall be time stamped upon receipt and held in a secure place until the due date. After the due date, a **register** of proposals shall be established. The **register** shall be open to public inspection, but the proposals will be seen only by authorized DIVISION staff and those selected by DIVISION to evaluate the proposals. The proposal(s) of the successful offeror(s) shall be open for public inspection for 90 days after the award of the contract(s). (e) Utah has a reciprocal preference law which will be applied against bidders bidding products or services produced in states which discriminate against Utah products. For details see Section 63-56 20.5 -20.6, Utah Code Annotated.

9. ANTI-DISCRIMINATION ACT: The offeror agrees to abide by the provisions of the Utah Anti-discrimination Act, Title 34 Chapter 35, U.C.A. 1953, as amended, and Title VI and Title VII of the Civil Rights Act of 1964 (42 USC 2000e), which prohibit discrimination against any employee or applicant for employment, or any applicant or recipient of services, on the basis of race, religion, color, or national origin; and further agrees to abide by Executive Order No. 11246, as amended, which prohibits discrimination on the basis of sex; 45 CFR 90 which prohibits discrimination on the basis of age, and Section 504 of the Rehabilitation Act of 1973 or the Americans with Disabilities Act of 1990, which prohibits discrimination on the basis of disabilities. Also offeror agrees to abide by Utah's Executive Order, dated March 17, 1993, which prohibits sexual harassment in the workplace. Vendor must include this provision in every subcontract or purchase order relating to purchases by the State of Utah to insure that the subcontractors and vendors are bound by this provision.

10. WARRANTY: The contractor agrees to warrant and assume responsibility for all products (including hardware, firmware, and/or software products) that it licenses, contracts, or sells to the State of Utah under this contract for a period of one year, unless otherwise specified and mutually agreed upon elsewhere in this contract. The contractor (seller) acknowledges that all warranties granted to the buyer by the Uniform Commercial Code of the State of Utah applies to this contract. Product liability disclaimers and/or warranty disclaimers from the seller are not applicable to this contract unless otherwise specified and mutually agreed upon elsewhere in this contract. In general, the contractor warrants that: (1) the product will do what the salesperson said it would do, (2) the product will live up to all specific claims that the manufacturer makes in their advertisements, (3) the product will be suitable for the ordinary purposes for which such product is used, (4) the product will be suitable for any special purposes that the State has relied on the contractor's skill or judgement to consider when it advised the State about the product, (5) the product has been properly designed and manufactured, and (6) the product is free of significant defects or unusual problems about which the State has not been warned. Remedies available to the State include the following: The contractor will repair or replace (at no charge to the State) the product whose nonconformance is discovered and made known to the contractor in writing. If the repaired and/or replaced product proves to be inadequate, or fails of its essential purpose, the contractor will refund the full amount of any payments that have been made. Nothing in this warranty will be construed to limit any rights or remedies the State of Utah may otherwise have under this contract.

11. DEBARMENT: The CONTRACTOR certifies that neither it nor its principals are presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction (contract) by any governmental department or agency. If the CONTRACTOR cannot certify this statement, attach a written explanation for review by the STATE.

12. ENERGY CONSERVATION AND RECYCLED PRODUCTS: The contractor is encouraged to bid Energy Star certified products or products that meet FEMP (Federal Energy Management Program) standards for energy consumption. The State of Utah also encourages contractors to bid products that are produced with recycled materials, where appropriate, unless otherwise requested in this solicitation.

13. GOVERNING LAWS AND REGULATIONS: All State purchases are subject to the Utah Procurement Code, Title 63, Chapter 56 Utah Code Annotated

1953, as amended, and the Procurement Rules as adopted by the Utah State Procurement Policy Board (Utah Administrative Code Section R33). These are available on the Internet at www.purchasing.utah.gov.

REQUEST FOR PROPOSAL
Newborn Screening Laboratory Information Management System
Solicitation # JG6003

PURPOSE OF REQUEST FOR PROPOSAL (RFP)

The purpose of this request for proposal is to enter into a contract with a qualified firm to provide a newborn screening laboratory information management system. It is anticipated that this RFP may result in a contract award to a single contractor.

This RFP is designed to provide interested offerors with sufficient basic information to submit proposals meeting minimum requirements, but is not intended to limit a proposal's content or exclude any relevant or essential data. Offerors are at liberty and are encouraged to expand upon the specifications to evidence service capability under any agreement.

BACKGROUND

The Newborn Screening Laboratory part of the Utah Public Health Laboratories has been using a PerkinElmer Life Sciences/Wallac laboratory information management system since 1999. Starting January 1, 2006, the Newborn Screening Laboratory and the Utah Department of Health Newborn Screening Follow-up Program will be introducing expanded screening for newborns. This requires both the lab and the follow-up program to update their information management system to accommodate the new tests. It also requires a system that can be updated, periodically by the lab staff and follow-up without incurring high programming costs so that the system meets the business needs of the Newborn Screening Program and its customers. With this scenario in mind, the decision has been made to write specifications for a new system and place an RFP for open bidding.

ISSUING OFFICE AND RFP REFERENCE NUMBER

The State of Utah Division of Purchasing is the issuing office for this document and all subsequent addenda relating to it, on behalf of Utah Department of Health. The reference number for the transaction is Solicitation #JG6003. This number must be referred to on all proposals, correspondence, and documentation relating to the RFP.

SUBMITTING YOUR PROPOSAL

One original and five identical copies of your proposal must be received at the State of Utah Division of Purchasing, 3150 State Office Building, Capitol Hill, Salt Lake City, Utah 84114, prior to the closing date and time specified. Proposals received after the deadline will be late and ineligible for consideration.

LENGTH OF CONTRACT

The Contract resulting from this RFP will be for a period of five years.

The contract may be extended beyond the original contract period for four additional years at the State's discretion and by mutual agreement.

The Newborn Screening Laboratory Management System must be completed and implemented before December 31, 2005, and ongoing technical support will continue throughout the remaining contract and extensions.

Payment to the successful bidder will be subject to appropriate (at least 25%) hold-backs to ensure timely and satisfactory completion of the project.

PRICE GUARANTEE PERIOD

All pricing must be guaranteed for the entire term of the contract. Following the guarantee period, any request for price adjustment must be for an equal guarantee period, and must be made at least 30 days prior to the effective date. Requests for price adjustment must include sufficient documentation supporting the request. Any adjustment or amendment to the contract will not be effective unless approved by the State Director of Purchasing. The State will be given the immediate benefit of any decrease in the market, or allowable discount.

STANDARD CONTRACT TERMS AND CONDITIONS

Any contract resulting from this RFP will include the State's standard terms and conditions. These may be accessed at:
http://www.purchasing.utah.gov/contractinfo/TermsAgency.pdf

QUESTIONS

All questions must be submitted in writing and may be submitted to Barbara Jepson via email at: bjepson@utah.gov or via fax at: (801)584-8486. Questions are due by 5:00 p.m. on July 5, 2005. Questions received after that date may not be answered. Answers will be given via an addendum posted on the Division of Purchasing website.

DISCUSSIONS WITH OFFERORS (ORAL PRESENTATION)

An oral presentation by an offeror to clarify a proposal may be required at the sole discretion of the State. However, the State may award a contract based on the initial proposals received without discussion with the Offeror. If oral presentations are required, they will be scheduled after the submission of proposals. Oral presentations will be made at the offeror's expense.

PROPRIETARY INFORMATION

The proposal of the successful offeror(s) becomes public information. Proprietary information can be protected under limited circumstances such as client lists and non-public financial statements. Pricing and service elements are not considered proprietary. An entire proposal may not be marked as proprietary. Offerors must clearly identify in the Executive Summary and mark in the body of the proposal any specific proprietary information they are requesting to be protected. The Executive Summary must contain specific justification explaining why the information is to be protected. Proposals may be reviewed and evaluated by any person at the discretion of the State. All materials submitted become the property of the State of Utah and may be returned only at the State's option.

DETAILED SCOPE OF WORK AND PROPOSAL REQUIREMENTS

See Attachment A, Newborn Screening – System Requirements.

PROPOSAL RESPONSE FORMAT

All proposals must be organized and tabbed with labels for the following headings:

1. **RFP Form**. The State's Request for Proposal form completed and signed.

2. **Executive Summary.** The one or two page executive summary is to briefly describe the offeror's proposal. This summary should highlight the major features of the proposal. It must indicate any requirements that cannot be met by the offeror. The reader should be able to determine the essence of the proposal by reading the executive summary. Proprietary information requests should be identified in this section.

3. **Detailed Response.** This section should constitute the major portion of the proposal and must contain at least the following information:

A. A complete narrative of the offeror's assessment of the work to be performed, the offeror's ability and approach, and the resources necessary to fulfill the requirements. This should demonstrate the offeror's understanding of the desired overall performance expectations. Clearly indicate any options or alternatives proposed.

B. A specific point-by-point response, in the order listed, to each requirement in the RFP.

4. **Cost Proposal.** Cost will be evaluated independently from the technical proposal. Please enumerate all costs on the attached Cost Proposal Form (Attachment F)

PROPOSAL EVALUATION CRITERIA

A committee will evaluate proposals against the following weighted criteria. Each area of the evaluation criteria must be addressed in detail in proposal.

WEIGHT	EVALUATION CRITERIA
30 %	Cost
20 %	System Configurability
20 %	Minimum and Detailed Requirements
10 %	Technical Support
20 %	Implementation Schedule

Attachment F

COST PROPOSAL

Bidder Name: _____

1. Provide a price for an enterprise software license as described in Attachment A for the products identified in your technical offer. This price must also include the first year of maintenance and support fees.

Enterprise Licensing Fee with first year of maintenance included: $_____

2. Provide pricing for maintenance and support fees for the second through fifth year of product ownership.

Maintenance and Support Fees – Year 2 $_____

Maintenance and Support Fees – Year 3 $_____

Maintenance and Support Fees – Year 4 $_____

Maintenance and Support Fees – Year 5 $_____

3. List the name, job title and hourly rate for any proposed consultants:

Name: _____ Title: _____ $ _____ / hour
Name: _____ Title: _____ $ _____ / hour
Name: _____ Title: _____ $ _____ / hour

4. Provide a per person training cost for any training that is recommended for employees that will be responsible for the installation and operation of the products included in this offer. Assume that the training will be held at one of your training facilities. Specify if the rate is hourly, daily, etc.

$_____ _____

Newborn Screening Laboratory Information Management System
RFP EVALUATION SCORESHEET

Firm Name: _____.

Evaluator: _____.

Date: _____.

Score will be assigned as follows:
0 = Failure, no response
1 = Poor, inadequate, fails to meet requirement
2 = Fair, only partially responsive
3 = Average, meets minimum requirement
4 = Above average, exceeds minimum requirement
5 = Superior

		Score	Weight (0-5)	Points
1. Cost **(30 points possible)**		----		*Inserted by Purchasing
2. System Configurability **(20 points possible)**		----		----
Compatibility with the Laboratory Information Management System	5 points		X1	
Compatibility with ARUP Systen	5 points		X1	
Compatibility with instrument interfaces	5 points		X1	
Other system configurability	5 points		X1	
3. Minimum and Detailed Requirements **(20 points possible)**		----	X4	----
4. Technical Support **(10 points possible)**			X2	
5. Implementation Schedule **(20 points possible)**			X4	
TOTAL EVALUATION POINTS	**(100 points possible)**		Total	

* Purchasing will use the following cost formula: The points assigned to each offerors cost proposal will be based on the lowest proposal price. The offeror with the lowest Proposed Price will receive 100% of the price points. All other offerors will receive a portion of the total cost points based on what percentage higher their Proposed Price is than the Lowest Proposed Price. An offeror whose Proposed Price is more than double (200%) the Lowest Proposed Price will receive no points. The formula to compute the points is: Cost Points x (2- Proposed Price/Lowest Proposed Price).

Newborn Screening - System Requirements

Brenden Anderle

Revision History
Revision 1.0 2005 Jun 06
Preliminary Final

Revision History
Revision 1.1 2005 Jun 08
Draft Final - Revisions added by Program committee.

Revision History
Revision 1.3 2005 Jun 21
Final - Revisions added by Program committee.

Describes system requirements for the Newborn Screening program in terms of the work-flow analysis and use-cases for each of the four areas of the program: [1] Sample Processing / Kit Management [2] Clinical Laboratory [3] Case Management - Patient Care [4] Third-Party Data Exchange

Table of Contents

1. Document Organization

The requirements presented are first those related to each of the areas of Newborn Screening Program, and then general requirements common to the system as a whole.

Basic use-case descriptions for each area are attached to provide more requirement details. UML Activity Diagrams are provided for work-flow processes.

1.1. About This Document

This document was created in XML using simplified DocBook. DocBook is an industry standard definition for technical documentation. Among the many advantages of DocBook, the primary use here is the document can be transformed (via XSLT) into other document formats with ease. This document is available in XML, HTML, XHTML, RTF (MS Word, WordPerfect), PDF (Adobe Acrobat) and PostScript.

1.2. Project Definition

The requirements and corresponding discussions are for a project that encompasses the efforts of the Newborn Screening Program of the Utah Department of Health.

Newborn Screening (NBS) is a service provided to newborn children that screens blood samples for certain childhood disorders, some of which may be life-threatening if not detected and treated immediately after birth. NBS is currently supported by a package of applications that provide demographic entry and sample tracking, sample preparation and results analysis, reporting of results and case management for cases that have been determined to be abnormal, those requiring ongoing services.

Early in 2005 the Governor announced that 30 new tests would be added, using the resources of a third-party lab. This along with other requirements has provided the impetus for the request for proposals for a new application that replaces the current set that can meet the needs stated herein.

There are four basic components to the NBS:

1. Sample Processing and Kit Management

   Specimen kits are sold and kit inventory managed. Specimens are received daily and the demographic and other identifying data is entered into the current application. The normal results are automatically reported and the process is overseen by the staff in this area.

2. NBS Laboratory testing of specimens

   Part of UPHL, the NBS Laboratory assigns the specimens to plate wells, and then preforms the various tests. Standards and controls are carefully monitored and used for results curve fitting analysis. Results are reported internally and to Case Management (abnormal or continuous services).

3. Case Management and Patient Care

   Patients with abnormal or on-going cases are carefully followed to ensure that abnormal results are confirmed or denied, and that families and providers are notified and provided with education materials and resources. The application provides methods for notification of abnormal cases, and provides the case managers task list of actions that follow a decision tree for the particular disorder.

4. Interactions with Outside Labs that provide testing services.

   These labs provide initial screening and confirmatory testing and report the results back to the system.

The proposed new application spans all of these areas in an integrated fashion and will help increase overall productivity and quality of service.

The requirements listed here detail the system and the required interactions with users and other actors.

1.3. Priorities

The following priority codes for functional requirements are defined below:

0 = Not required by this program area

1 = Critical

2 = Important

3 = Nice to have

4 = Future feature or Wish

2. Process Requirements

The application requirements are described in the tables below. Each major application component has a set of tables. Most of the requirements come from the use-case analysis. Some of these requirements refer to the existing system but are included here for explicit clarity.

2.1. Sample Processing / Kit Management

2.1.1. Data Entry and Validation

ID	Requirement	Priority
2.1.1.1	Ability to enter patient demographic data from kit card, see use-cases "Enter a First Screen Card", "Enter a Second Screen Card"	1
2.1.1.2	Names cannot be changed from one specimen to another. If a second specimen is received, the data for the 1st should not automatically change.	1
2.1.1.3	Mother and baby's last name should not be the same by default, but should be a user-defined option.	1
2.1.1.4	Must be able to print mailing labels in a user-defined layout or export mailing list in user-defined format from address tables.	1
2.1.1.5	Demographic data must be dual entered using data-input screens optimized for speed and accuracy. The dual entry fields to be determined supervisory UDOH staff.	1
2.1.1.6	Separate fields for Hospital and Submitter (identity and address of requestor/sender of the specimen). Normally these would be the same. Mailers are sent to the Submitter.	1
2.1.1.7	Upon receipt, kit bar codes are read before assignment of the accession number to determine if the specimen is a recall sample.	2
2.1.1.8	Ability to View Demographic Data Edits	1
2.1.1.9	Ability to transmit Normal Results to the submitter / provider and to track the process.	1
2.1.1.10	Ability to Add, Edit, Delete Submitter	1
2.1.1.11	Ability to Distribute Kits, and update inventory	1
2.1.1.12	Ability to Edit Test Requests	1
2.1.1.13	Ability to Link / Unlink specimens, when kit id's or demographics don't match.	1
2.1.1.14	Ability to Annotate Patient Demographics to track anomalies	1
2.1.1.15	Ability to Maintain Kit Inventory, track stock-on-hand, and be able to order new stock.	1

2.1.2. Generation of Accession Numbers

Currently, the generation of the numbers as bar codes is handled by a separate application. However general bar code requirements are below:

ID	Requirement	Priority
2.1.2.1	Must have the ability to produce bar codes that include both alpha-numeric character data and a human readable code that is printable.	1
2.1.2.2	Must have the ability to produce bar codes in a user-defined structure. The bar code itself does not contain the date. The last two digits of the accession number / bar code must be a randomly generated number used to validate the machine-readable code.	1

2.1.3. Reports and System Outputs

The following are the reports that are currently defined for Sample Receiving / Kit Management:

ID	Requirement	Priority
2.1.3.1	Kits not Linked	1
2.1.3.2	Dual Entry Not Done	1
2.1.3.3	Invalid Dates	1
2.1.3.4	Failed Faxing	1
2.1.3.5	Invalid Birth dates	1
2.1.3.6	Linked Kits	1
2.1.3.7	Requester File	1
2.1.3.8	Kit Inventory	1
2.1.3.9	Ability to Generate Saved and User-defined Queries - see this use-case for list of defined queries	1
2.1.3.10	Normal Test Result	1
2.1.3.11	First Specimen, 2nd Specimen	1
2.1.3.12	Reprint 1st, 2nd	1

2.1.4. Use Case Descriptions

See Sample Processing Use Cases (Attachment B)

2.1.5. Work Flow - UML Activity Diagrams

Figure 1. Sample Processing - Kit Distribution

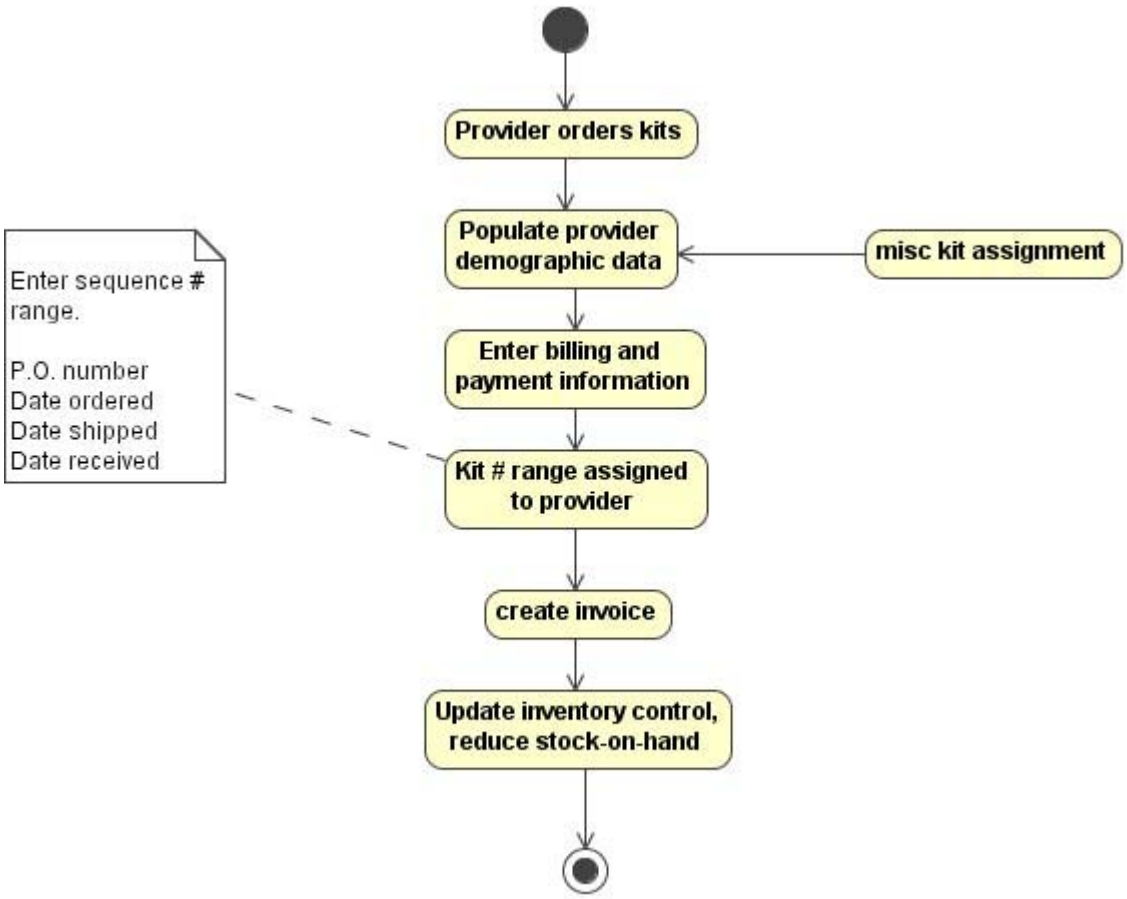
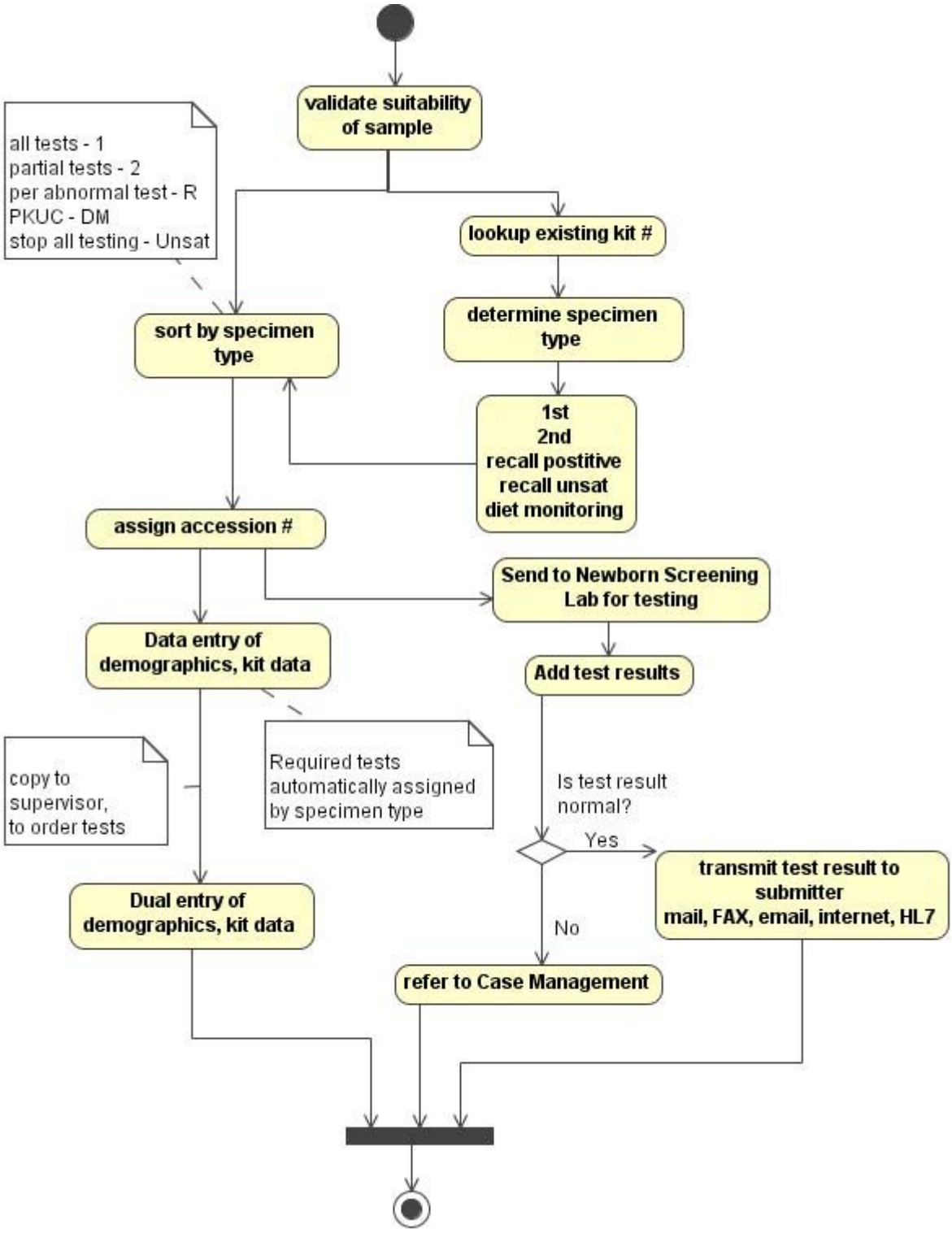


Figure 2. Sample Processing - Work Flow



2.2. NBS Laboratory

In general, the NBS system must integrate with the existing Perkin Elmer (PE) instrumentation already established in the NBS Laboratory. The current system performs the following processes:

The following existing components in the current system will be included in the new system:

Punch, Reader and PE application that interfaces with the instruments (Multicalc / Assay Viewer). Specimen identification data is read from Sample Receipt. The persistent store is MS SQL Server 2000 located locally within the campus. Results are written to the database tables on the same database server.

The new system will use the legacy MS SQL Server as an interface point.

Requirements for the enhancements to this system are:

2.2.1. Integration with Current Instrumentation

ID	Requirement	Priority
2.2.1.1	Ability to track six type of specimens: F (First screen) S (Second screen) R (Recall), D (Diet), U (Unsatisfactory), (T) Transfusion	1
2.2.1.2	Ability to capture results for confirmatory test: • T4 = lowest 10% and between 4 & 8 ug/dl Result <= 4 is abnormal • Galt <= 4 U/gHb • Hb - Any test that is not FA • CAH - TBD • BIOT - TBD	1
2.2.1.3	Capture results for repeat testing • T4 >= 39 or 0 • Galt >= 39 • Hb - Technician determined. • CAH - TBD • BIOT - TBD	1
2.2.1.4	Ability to capture results for reporting	1
2.2.1.5	Ability to capture QC data and process averaging, single point averages or individual values.	1
2.2.1.6	Ability to add new or remove existing tests and analysis (curve fitting) - user extensible.	1
2.2.1.7	Ability to assign a case to Case Management even if test determination is normal.	1
2.2.1.8	Ability to integrate with existing MS SQL Server. The PE system writes results into this database. It is physically located on the Utah Public Health Laboratory campus.	1
2.2.1.9	Ability to report a result as user-defined status e.g.: QNS(Quantity Not Sufficient), Normal, Abnormal, equivocable, data value, or character description	1
2.2.1.10	Inventory Management is available from a vendor, then it would be useful. Material management is a low priority feature.	3

2.2.2. Reports and System Inputs & Outputs

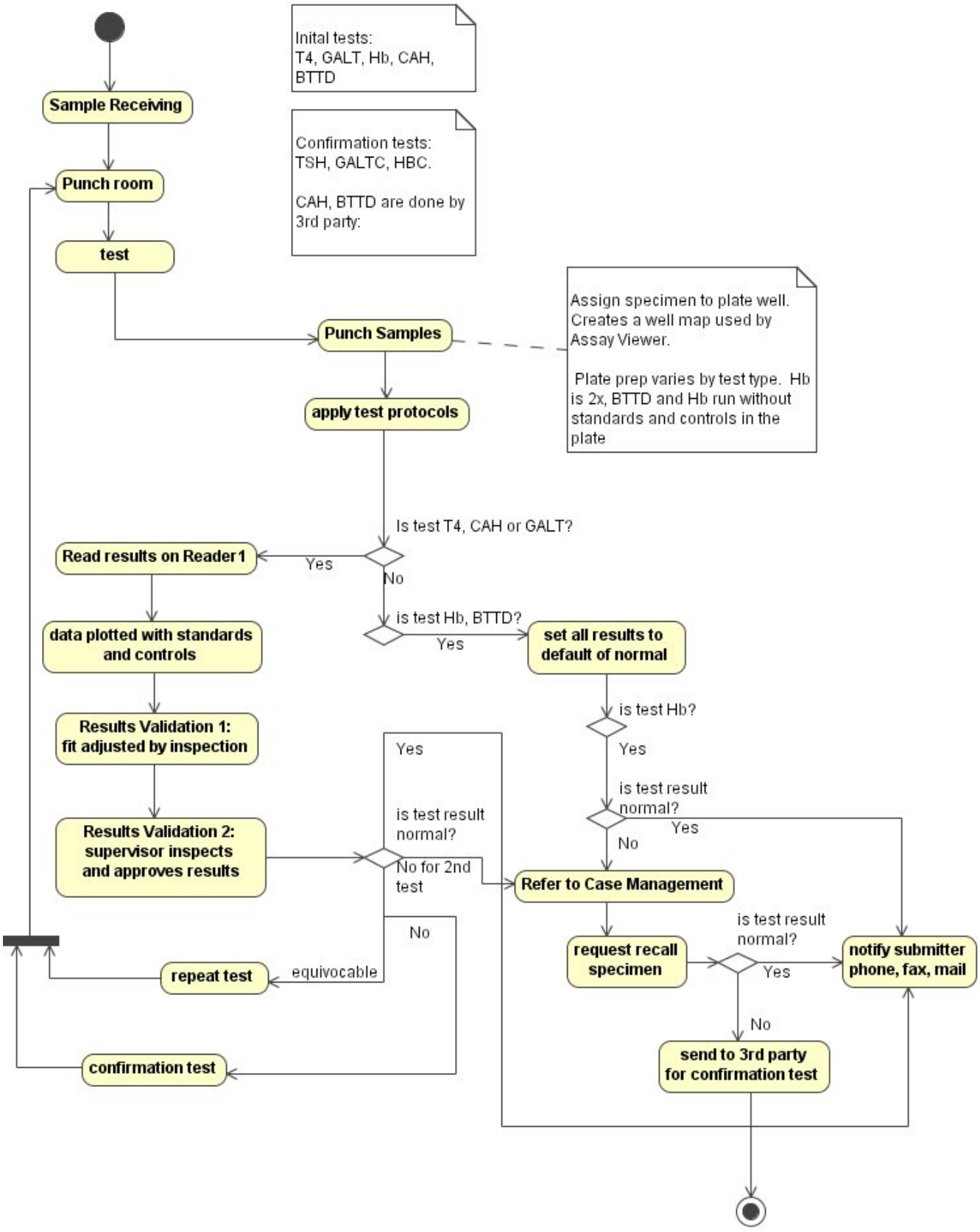
ID	Requirement	Priority
2.2.2.1	Ability to query the system to produce named ad hoc queries.	1
2.2.2.2	Ability to export demographic data to third party via HL7 spec 2.3.1 + (See Third Party Data Exchange)	1
2.2.2.3	Ability to import third party test results and initiate transfer of cases to Case Management - Patient Care	1
2.2.2.4	Defined daily reports: Positive results, Confirmation tests, repeat tests, positives per test type, unsatisfactory sample count, MTD, YTD cumulative counts of each statistic. Pending 5 + days with query parameters to adjust date range Testing Complete No Report - no provider report was generated. • Find Baby • New Unsats	1

2.2.3. Use Case Descriptions

See NBS Laboratory Use Cases (Attachment C)

2.2.4. Work Flow - UML Activity Diagrams

Figure 3. NBS Laboratory Work Flow Process



2.3. Case Management - Patient Care

2.3.1. General Application Requirements

ID	Requirement	Priority
2.3.1.1	Field name and datum item terminology must be internally consistent (intra-application and inter-application)	1
2.3.1.2	Must allow for unlimited number of annotation (charting notes, system notes, decision reasons) fields must be unlimited for both number of entries and length of entry	1
2.3.1.3	All annotation fields must allow for entries to be > 1 Mb in length.	1
2.3.1.4	Annotation fields must be printable in order that is user-defined: e.g. Chronological	1
2.3.1.5	Annotation fields must automatically insert or display the following: date time stamp, user name of modifier (from login authentication)	1
2.3.1.6	All demographic or HIPAA related fields must be allowed to be marked as opt-out for third-party data export or sharing	1
2.3.1.7	Users with admin role must be able to create, edit or delete all descriptive data displayed in the user interface, in drop down boxes, pick-lists or other UI controls.	1
2.3.1.8	Users must have the ability to add or view confirmation test results.	1
2.3.1.9	Must have the ability to view all notes, both lab and case management in a single screen.	1
2.3.1.10	Ability for the Lab Manager to order a single test on a specimen.	1
2.3.1.11	Ability to create letters using industry standard word processing application e.g. MS Word as letter creation with merge fields and to lookup table for field names as a source for the merge data.	1
2.3.1.12	Integrate with Fax Server to send faxes without printing	3
2.3.1.13	Ability to preserve all user and system activities as legal documentation	1
2.3.1.14	Baby's medical home can be edited - the current medical home can be added and marked as such to allow letters etc to be sent to current address.	1
2.3.1.15	Ability to have multiple diagnostic categories for each determination.	1
2.3.1.16	Case Managers must be able to correct wrong entries only for diagnosis and reason closed.	1
2.3.1.17	Must have data field for deceased status and date.	1
2.3.1.18	Must have field for diet prescription	1
2.3.1.19	Must have field for father's name	1
2.3.1.20	All information on demographic card is available for that case to the Case Manager	1

2.3.2. Case Management

Some of these requirements reference elements of the use-cases and may be duplicated, but are here for completeness.

ID	Requirement	Priority
2.3.2.1	Ability to have Notification of a New Case	1
2.3.2.2	Ability to View and Search Active Cases	1
2.3.2.3	Ability to Perform a Task Action or change location in the decision tree	1
2.3.2.4	Ability to Create, Update a Provider Contact	1
2.3.2.5	Ability to Change the Status of an Active Case	1
2.3.2.6	Ability to Annotate an Inactive Case	1
2.3.2.7	Ability to Create Notification Letter and add custom paragraphs specific to selected case.	1
2.3.2.8	Ability to View and Report the Case History	1
2.3.2.9	Ability to Generate Reports	1
2.3.2.10	Ability to Generate Letters	1
2.3.2.11	Create Reports	1
2.3.2.12	Create Letters	1
2.3.2.13	Create, Edit or Delete Decision Tree And Actions	3
2.3.2.14	All current follow up actions are available on a worksheet.	1
2.3.2.15	Sorting in the worksheet can be done on any category • Kit ID Number • Baby's Name • Sex • Date of Birth • Mother's Name • Action Needed • Date action is to be done Choosing one or the actions opens up the case on the selected patient.	1
2.3.2.16	Each determination (result) is sorted by disorder	1
2.3.2.17	Each case within a disorder is listed alphabetically. However, sort order may be changed to be by other categories: • Kit ID Number • Baby's Name • Sex • Date of Birth • Date Created	1

2.3.3. Reports and System Outputs

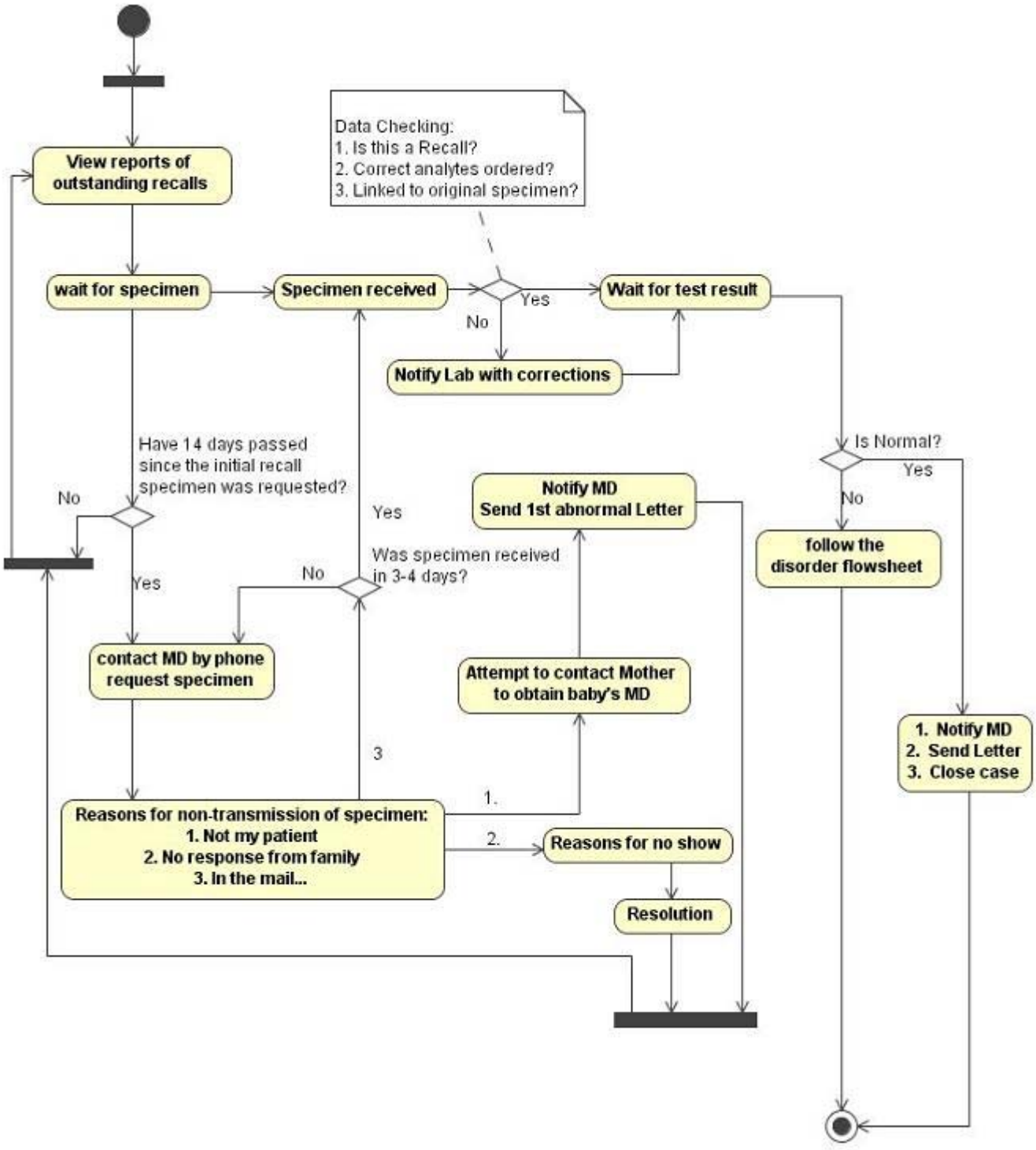
ID	Requirement	Priority
2.3.3.1	Need to be able to add letter content that is in WYSIWYG format - letters are very customized.	1
2.3.3.2	Integrate with Fax Server -	3
2.3.3.3.	Currently defined letters (41) for disorders (using the user-defined file names):	1
2.3.3.4	Acylcarnitine: letms1, letms2, letms3, letms5	1
2.3.3.5	BIOT: leb1, leb2, leb3, leb4, leb5	1
2.3.3.6	CAH: leca1, leca2, leca3, leca4	1
2.3.3.7	GALT: legal1, legalgn, legalDn, legal5, .legal4, legal5d	1
2.3.3.8	HEMO: lehb1, lehb2, lehb3, lehb4, lehb5, lehb7, lehbsctrait, lehb9barts, lehb???	1
2.3.3.9	HYP: lehypcv, lehy2s, lehyp2	1
2.3.3.10	PKU: lepku1, lepkunormal, lepku, lepku3, lepku4, lepku5, lepku5d	1
2.3.3.11	Transfusion: letr1first, letr1second, letrs4	1
2.3.3.12	Unsat: leina3, leina1, leina4, leina5	1
2.3.3.13	Ability to perform saved and user-created queries. These queries will be used to report for internal and external entities.	1
2.3.3.14	Must create reports for NNSIS and MCH block grant (annual basis)	2
2.3.3.15	Must create reports for statistical interpretation, QA, QC and others TBD. Currently defined queries are: • New Diets • New 1st Transfused • New 2nd Transfused • New 1st Recall • New 2nd Recall • Find Baby • New 1st Positives • New 2nd Positives • New Unsats	1
2.3.3.16	Additions to Testing Report - Any additions to testing that require a recall automatically transfer to Case Management and populate a separate report.	1

2.3.4. Use Case Descriptions

See Case Management Use Cases (Attachment D)

2.3.5. Work Flow - UML Activity Diagrams

Figure 4. Daily Recall Process - Work Flow Process



2.4. Third-Party Data Interface

2.4.1. Laboratory Data Exchange

UPHL accesses third party's system via FTP or TCP/IP sessions through VPN connectivity.

The third party's Interface Engine is bi-lingual, it can talk Flat file, HL7 or other communications protocol. But, it is predominantly HL7. It's the very same server that is used for file-driven submission and result reporting currently used by UPHL

The required method of communication is TCP/IP using the HL7 v. 2.3.1 Minimal Layer protocol.

ID	Requirement	Priority
2.4.1.1	Ability to send message containing demographic data to third party via HL7 spec 2.3.1 + and acknowledge receipt (per HL7 spec.)	1
2.4.1.2	Ability to receive messages containing test results (determination) from a third party via HL7 spec 2.3.1 + and acknowledge receipt (per HL7 spec.)	1
2.4.1.3	Message system should allow for both near-time interactions and batch mode message transfer.	1
2.4.1.4	Message system should support all standard features - for a reference implementation see J2EE JMS service.	1
2.4.1.5	Message system should allow messages to be enqueued and delivered or notify the sender that message was delivered or was undeliverable.	1
2.4.1.6	Ability to disallow message transfer if data is incorrect and notify user of problem.	1

2.4.2. UDOH Data Exchange - CHARM

ID	Requirement	Priority
2.4.2.1	Ability to be integrated with Child Health Advanced Records Management (CHARM) server to securely share and retrieve necessary information with other UDOH programs. The shared information will be described in formal Data Sharing Agreements	1
2.4.2.2	CHARM is an integration infrastructure that maintains a virtual child health profile on its core server to facilitate record matching on disparate systems. Assist in the CHARM interface specification for the proposed application: • Shared data model • Data mapping • Defined services (e.g. UDDI-type registry entry) • Communications - Services and Protocols CHARM integration allows each participating application to generate queries and receive responses within the constext of each respective application	1

2.4.3. Reports and System Outputs

ID	Requirement	Priority
2.4.3.1	Ability to show message logs, messages sent and received	1
2.4.3.2	Ability to show transit time and total message response time	2
2.4.3.3	Ability to report on total message volume by requests and results.	2

2.4.4. Use-Case Descriptions

Data Exchange With 3rd Party use-case analysis are described here.

2.5. General Application Requirements

2.5.1. System Availability and Architecture

Due to the time-sensitive nature of the testing and notification, the application must be a high-available system.

ID	Requirement	Priority
2.5.1.1	Application must be available 99.999% of time	1
2.5.1.2	Application must provide for automatic or simple manual fail over to secondary site (currently the Cannon Building) in the case of primary site problems or disaster.	1
2.5.1.3	Technical architecture may be a web application, to allow usage from multiple UDOH sites, and to reduce total cost of ownership.	2
2.5.1.4	Legacy database is MS SQL Server 2000.	1
2.5.1.5	The application may be delivered in phases, with the key requirements delivered in earlier phases, as defined by UPHL and Case Management.	2

2.5.2. General Requirements

ID	Requirement	Priority
2.5.2.1	Field name and datum item terminology must be internally consistent (intra-application and inter-application)	1
2.5.2.2	Must allow for unlimited number of annotation (charting notes, system notes, decision reasons) fields must be unlimited for both number of entries and length of entry	1
2.5.2.3	All annotation fields must allow for entries to be > 1 Mb in length.	1
2.5.2.4	Annotation fields must be printable in order that is user-defined: e.g. Chronological	1
2.5.2.5	Annotation fields must automatically insert or display the following: date time stamp, user name of modifier (from login authentication)	1
2.5.2.6	All demographic or HIPAA related fields must be allowed to marked as opt-out for third-party data export or sharing	1
2.5.2.7	Users with admin role must be able to create, edit or delete all descriptive data displayed in the user interface, in drop down boxes, pick-lists or other UI controls.	1
2.5.2.8	Users must have the ability to add or view confirmation test results.	1
2.5.2.9	Must have the ability to view all notes, both lab and case management in a single screen.	1
2.5.2.10	Ability for the Lab Manager to order a single test on a specimen.	1
2.5.2.11	Ability to preserve all user and system activities as legal documentation	1
2.5.2.12	Must have data field for deceased status and date.	1
2.5.2.13	User manuals and instructional materials must be provided upon installation of software before the final user acceptance tests are performed.	1
2.5.2.14	User domain experts will assist in the design and approve all UI screens.	2

2.5.3. System Configurability

ID	Requirement	Priority
2.5.3.1	All system values should be contained in a single configuration file or similar mechanism	1
2.5.3.2	Users with appropriate privileges should have maintenance screens to add, edit all descriptive fields and lists.	1

2.5.4. Security

The NBS application will be hosted and secured by UDOH IT Services. The primary production application and database servers will be hosted at the UPHL campus. The backup application and database servers will be hosted at the main UDOH facility, approximately 5 miles from the UPHL. UDOH IT services will provide a secure environment for the system to reside. Additionally, the NBS must provide the following security:

ID	Requirement	Priority
2.5.4.1	Ability to create and maintain individual user specific security tables containing user ID and password information that is accessible by administrator level security.	1
2.5.4.2	Ability to restrict user passwords to HIPAA-compliant combinations of characters of a standard minimum length	1
2.5.4.3	Ability to track user password revisions and force users to change their passwords at UPHL determined intervals	1
2.5.4.4	Ability to terminate log-on screen after UDOH determined number of unsuccessful tries by a user to log in	1
2.5.4.5	Ability to automatically log off idle workstations after a predetermined period of time	1
2.5.4.6	Ability to enable a user automatically logged off to log back in and have the system reset to the same screen the user was on when the automatic log off occurred	1
2.5.4.7	Ability to limit workstations from which the system can be accessed.	1
2.5.4.8	Ability to define whether a user can access system from a remote site	1
2.5.4.9	Ability to prevent a user from being logged on to multiple workstations at the same time	1
2.5.4.10	Ability to limit hours of access for individual users and lock them out of the system during non-authorized hours	1
2.5.4.11	Ability to create an audit trail of who, when, where, and what functions and data were accessed by a specific user	1
2.5.4.12	Ability to create an audit trail of who and when information is viewed regarding patients, their tests and test results	1
2.5.4.13	Ability to conform to any other HIPAA security conditions adopted by a particular PHL as a part of its privacy and security documentation	1

2.5.5. User Rights and Privileges

See the use-cases for the identified user roles (Attachment E). The application should be able to define new roles as needed, and be able to assign privileges to the role.

ID	Requirement	Priority
2.5.5.1	Ability to create rights and privilege groups by user role	1
2.5.5.2	Ability to limit user rights by functions and screen displays	1
2.5.5.3	Ability to control which users have the right to update specified data sets and track the data updated	1
2.5.5.4	Ability to automatically lock certain records at some specified point after creation (test results for example)	1
2.5.5.5	Ability to include add/delete/edit/read only limits on user rights	1

2.5.6. Screen Access and Navigation

User rights notwithstanding, this section specifies requirements regarding system screen access and navigation.

ID	Requirement	Priority
2.5.6.1	Ability to access any allowed function from any workstation on the system	1
2.5.6.2	Ability to access various screens through the use of menus and appropriate icons on various screens	1
2.5.6.3	Ability to move easily from one screen to another utilizing screen appropriate icons or function keys	1
2.5.6.4	Ability for off-site customers to access limited read-only fields or portions of the NBS	4

2.5.7. Bar Code Usage

ID	Requirement	Priority
2.5.7.1	Ability to support a variety of Bar Code labels for different uses that contain use-specific codes, and be human readable	1
2.5.7.2	Ability to print Bar Code labels on variety of printers	1
2.5.7.3	Ability to print user-defined number of copies	1
2.5.7.4	Ability to support multiple Bar Code standards	1
2.5.7.5	Ability to print bar codes labels from a web browser - for third-party laboratories who submit test requests remotely	2

2.5.8. Data Archiving

ID	Requirement	Priority
2.5.8.1	Ability to support multi-tiered archiving with a progression of movement from the system hard drive to other forms of data storage	1
2.5.8.2	Ability to find and retrieve specific archived data sets	1
2.5.8.3	Ability to delete archived data sets at end of specified holding periods	1
2.5.8.3	Ability to schedule daily or user-defined periodic backups	1

2.5.9. Monitor and Alert System

ID	Requirement	Priority
2.5.9.1	Ability to send system alerts when user-defined events (specified by administrator or lab manager) occur e.g. test ordered, specific result occurred, QC failure, etc	2
2.5.9.2	Ability to send external alerts (via email and/or electronic messaging) to an external party when a specific event occurs.	2

2.5.10. System Events

ID	Requirement	Priority
2.5.10.1	Ability to schedule and perform events and view a log of events performed. This includes reports, backups, etc.	1

2.5.11. Provider and Submitter Management

ID	Requirement	Priority
2.5.11.1	Ability to maintain a master database of providers and submitter information including name (clinic, physician) submitter id, billing address, mailing address (for results), phone number for contacts, fax numbers	1

2.5.12. Data Migration

ID	Requirement	Priority
2.5.12.1	Ability to map existing data, from current PE system (MS SQL Server 2000), to the replacement NBS data structure and migrate legacy data to that format	1
2.5.12.2	Ability to use application's reporting tools to query and report on legacy data	1

2.6. Field Entry and Editing and System Table Maintenance

2.6.1. Field Value Entry and Editing

ID	Requirement	Priority
2.6.1.1	Ability to provide data validation that assures consistency and accuracy of captured information. :	1
2.6.1.2	Ability to enter the value desired directly or from a drop down table of valid values through standard mouse selection procedure	1
2.6.1.3	Ability to require mandatory fields to be filled before user can exit the screen, along with prompts or highlights that enable the user to quickly see which fields need to be completed	2
2.6.1.4	Ability to define data entry fields for dual entry with separate verification pass prior to accepting the data set. Data entry fields are defined by the UPHL supervisor for second screen.	1

2.6.2. Other Field Editing: Editing of non-table fields

ID	Requirement	Priority
2.6.2.1	Ability to apply alpha/numeric edits	1
2.6.2.2	Ability to test for valid numeric value range	1
2.6.2.3	Ability to perform selected correlation edits between fields	1
2.6.2.4	Ability to edit for valid dates and reasonable date ranges, use date picker screen component to reduce error	1
2.6.2.5	Ability to insert default values for any code or non code field	1
2.6.2.6	Ability to default value for current date and time in all appropriate fields that are generated from the system clock, but allow user over-ride. In this case use the database server's time stamp,not the local machines.	1

2.6.3. System Maintenance

Maintenance of all NBS system tables for which the user has the responsibility for populating

ID	Requirement	Priority
2.6.3.1	Ability to control access to the system tables by authorized administrative personnel	1
2.6.3.2	Provide a GUI interface to allow authorized users to apply and modify codes for samples, test results, providers etc.	1
2.6.3.3	Ability to maintain the value set for any table	1
2.6.3.4	Ability to time-stamp any table where changes are only valid starting on a specific date. Code set that will be presented to the user will correspond to the system date.(database server date)	1

2.7. Reporting and Query Capability

2.7.1. General Reporting

ID	Requirement	Priority
2.7.1.1	These requirements are for standard, normal predefined reports embedded in the NBS	1
2.7.1.2	Ability to provide Workload Reports (periodic – weekly, monthly, yearly, etc. – workload reports that will indicate separate counts of specimen/samples received and tests performed for each analytical area, including standard and controls.)	2
2.7.1.3	Ability to provide Work Time Unit reports (reports that calculate the amount of labor it took to run the tests). The system should also be flexible enough so the laboratorians can add, delete, or change tests and work time units as needed.	2
2.7.1.4	Ability to provide Quality Assurance Reports. The system should produce reports based on any of data fields and the comment fields where additional QA information will be stored. Examples of QA reports include information about unsatisfactory specimens/samples, specimen/sample rejection, improperly labeled specimen/samples etc.	1
2.7.1.5	Ability to provide Turn-around Time Reports (reports showing the turn-around times for specific tests or test groups, including the average turn-around times plus the number that meet, exceed, and are less than predetermined turn-around times)	2
2.7.1.6	Ability to provide Quality Control Reports (reports showing periodic summaries of QC results with detailed reports of exceptions including detailed listings of QC results for a particular date range, as well as tracking changes in QC measures and who made the changes)	1

2.7.2. Report Generation Strategy (Internal and Export)

ID	Requirement	Priority
2.7.2.1	Ability to provide a reports menu from which the user can select and run standard (predefined) system reports	1
2.7.2.2	Ability to produce reports without affecting the system performance	1
2.7.2.3	Ability to create user query reports utilizing a standard query tool compatible with the system database architecture	1

2.7.3. General Query Capabilities

Maintenance of all NBS system tables that the user has the responsibility for populating

ID	Requirement	Priority
2.7.3.1	Ability for users to create queries based on key data fields	1
2.7.3.2	Ability to perform name searches utilizing soundex approaches	2
2.7.3.3	Ability to access query function screens from screens where it would be logical to do so rather than having to return to a system menu	2
2.7.3.4	Ability to query for any specific test request test status	3

2.8. Work Flow Process Diagrams

2.8.1. Case Management - Patient Care

Included here are process diagrams (UML Activity Diagrams) for each disorder tested and managed by NBS. These diagrams represent the same actions available to the Case Manager to follow the case and update its status.

2.8.1.1. Activity Diagrams (UML)

The following are the case-management processes for the current disorders.

Figure 5. Acylcarnitine Work Flow Process

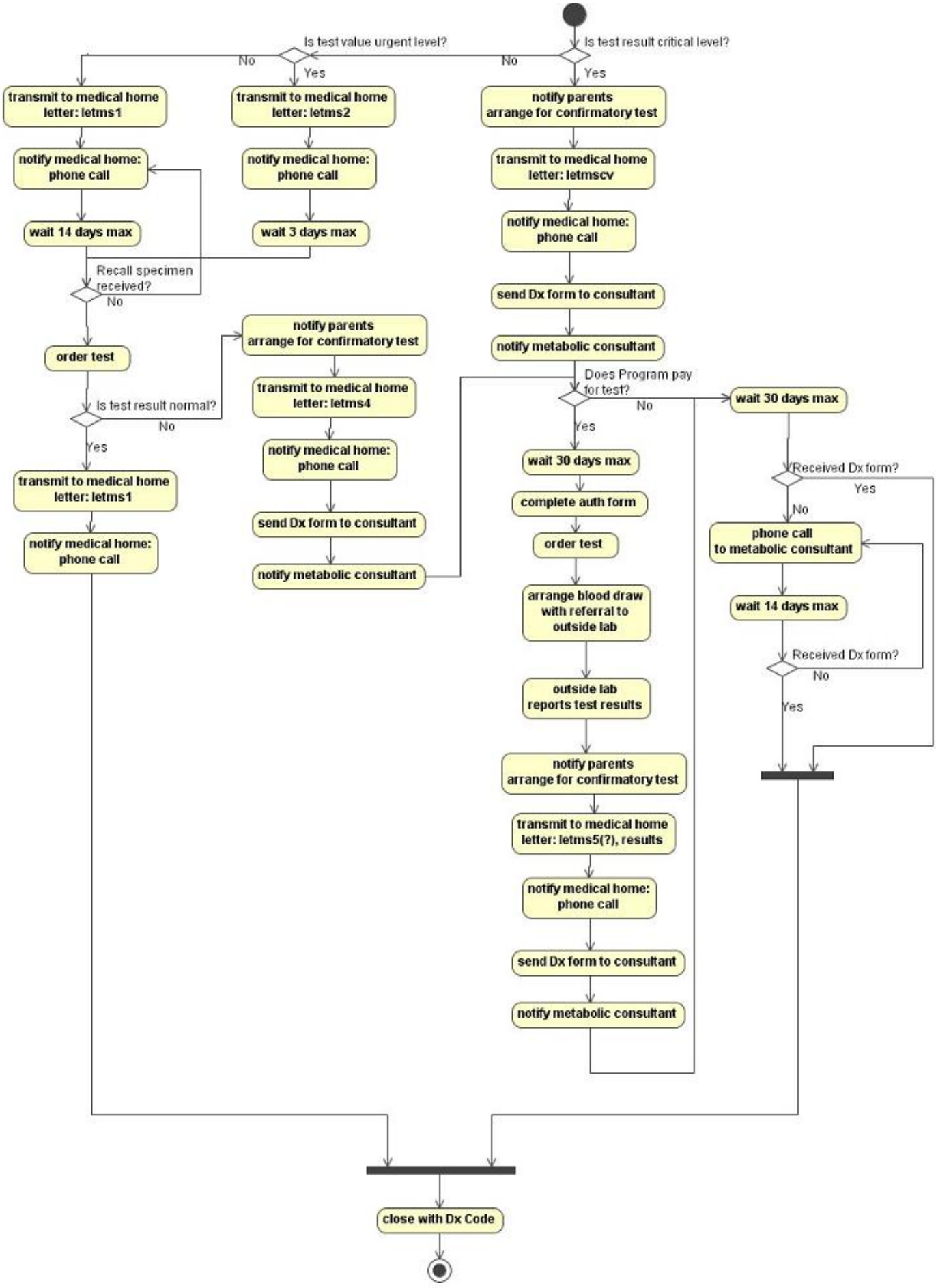


Figure 6. Biotinidase Work Flow Process

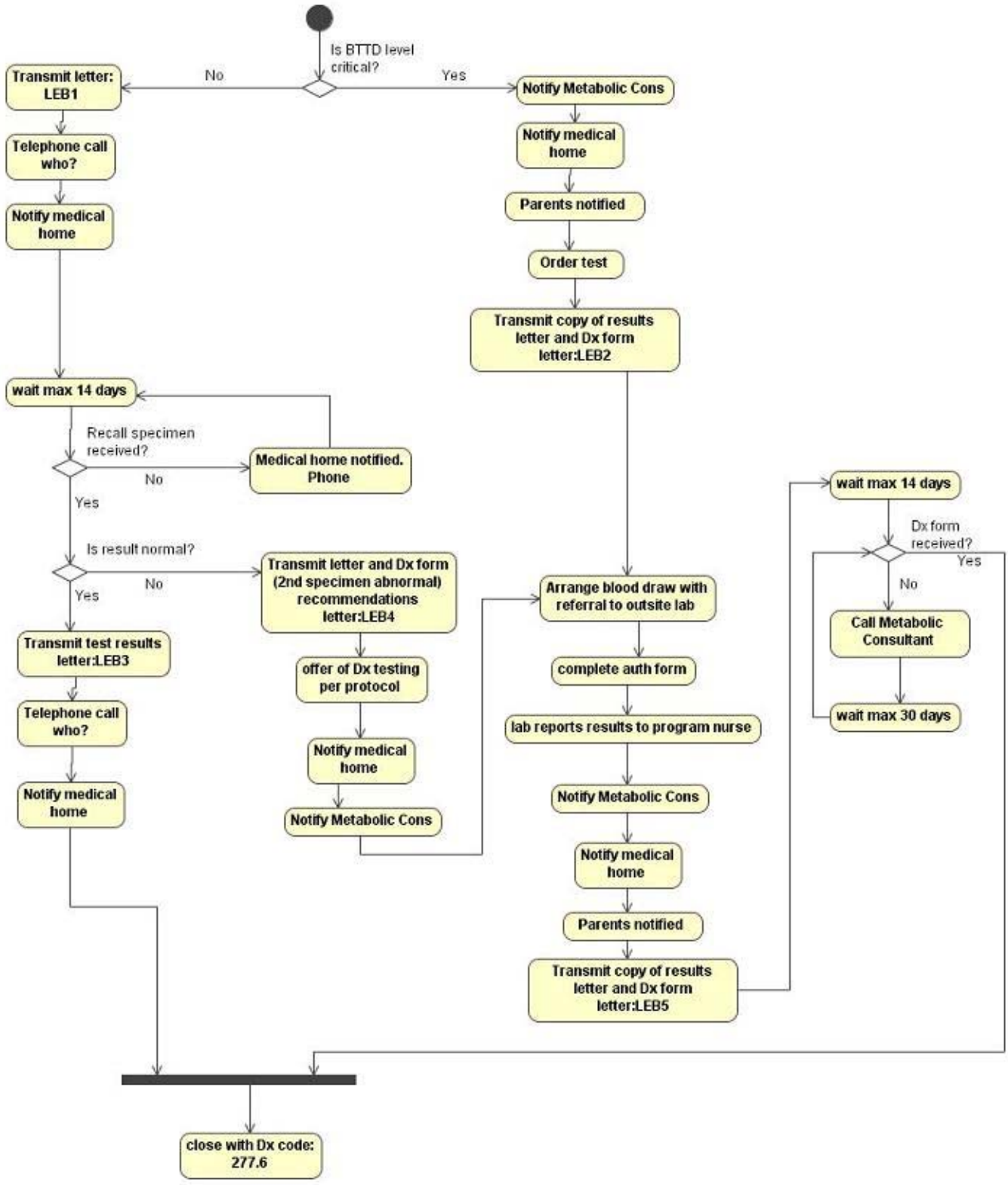


Figure 7. CAH Work Flow Process

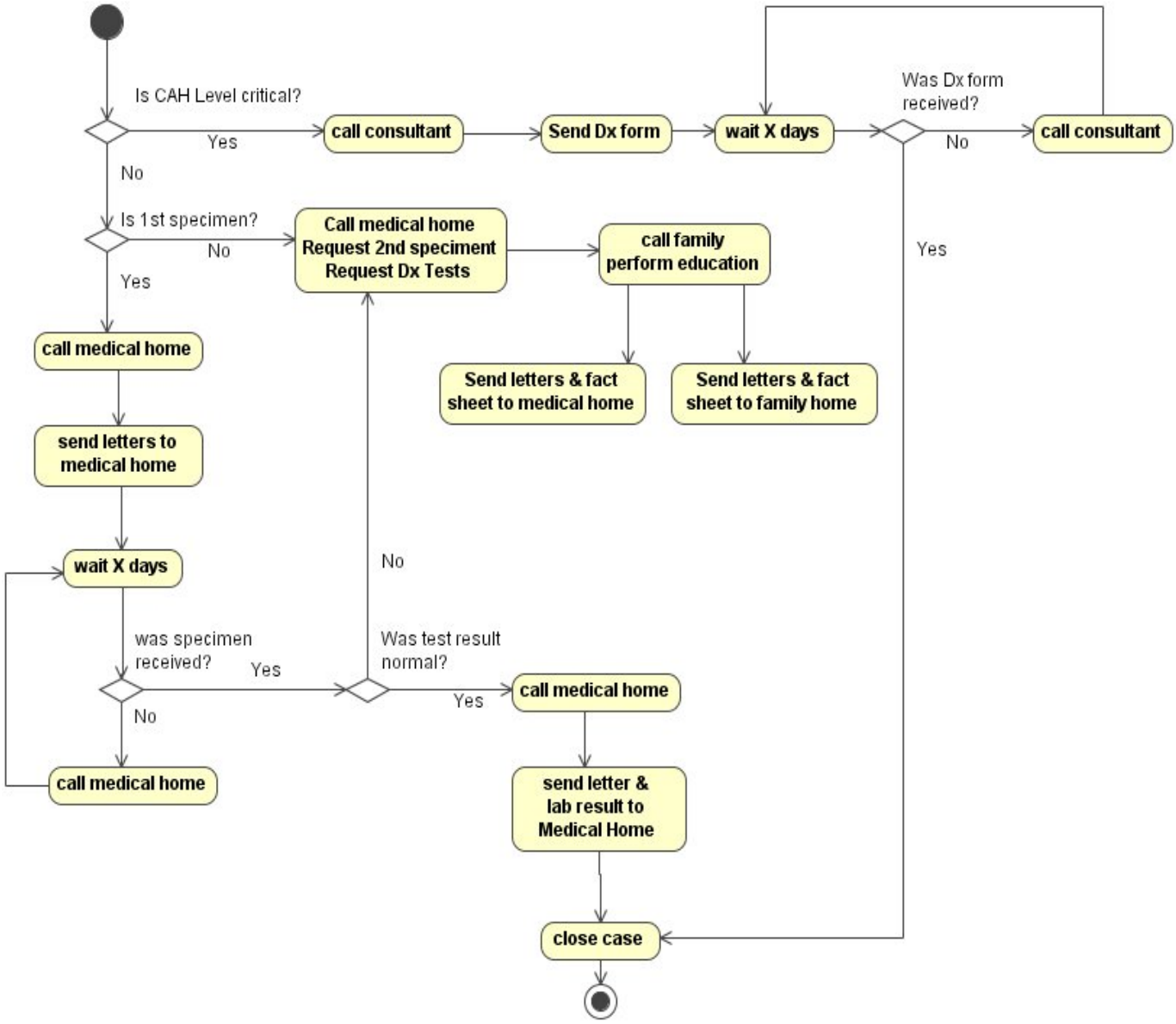


Figure 8. GALT Work Flow Process

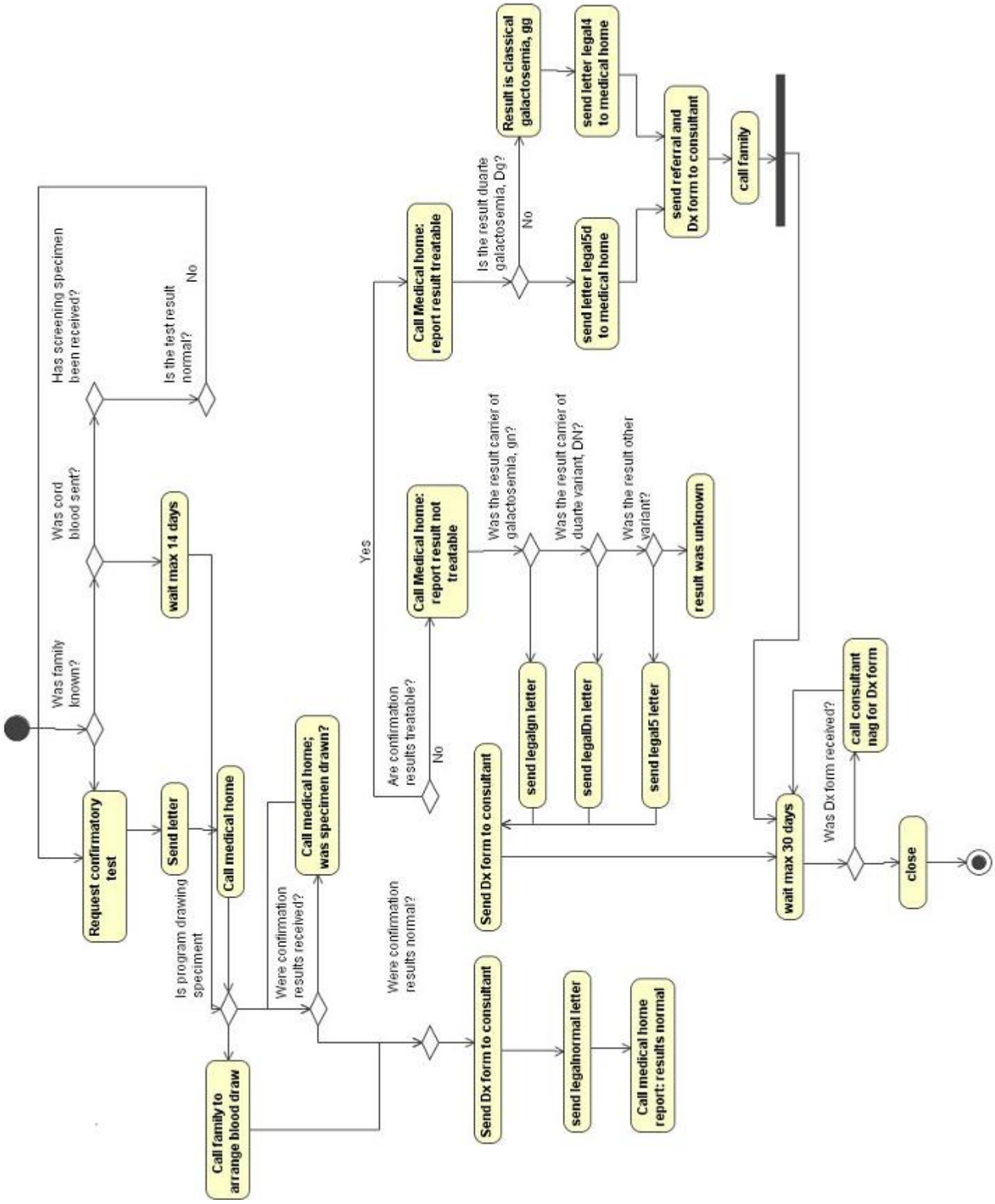


Figure 9. Hemoglobinopathies Work Flow Process

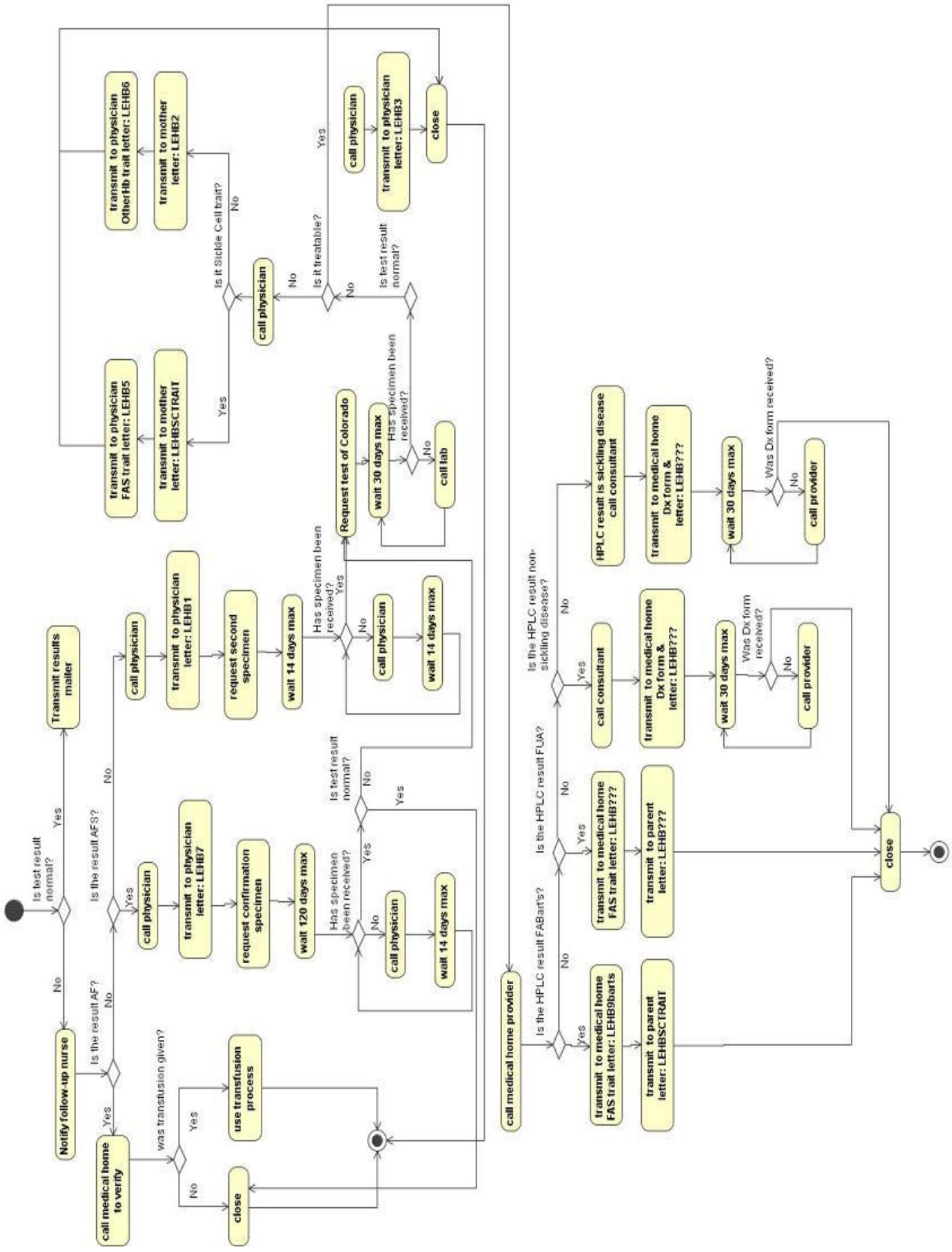


Figure 10. HYP Work Flow Process

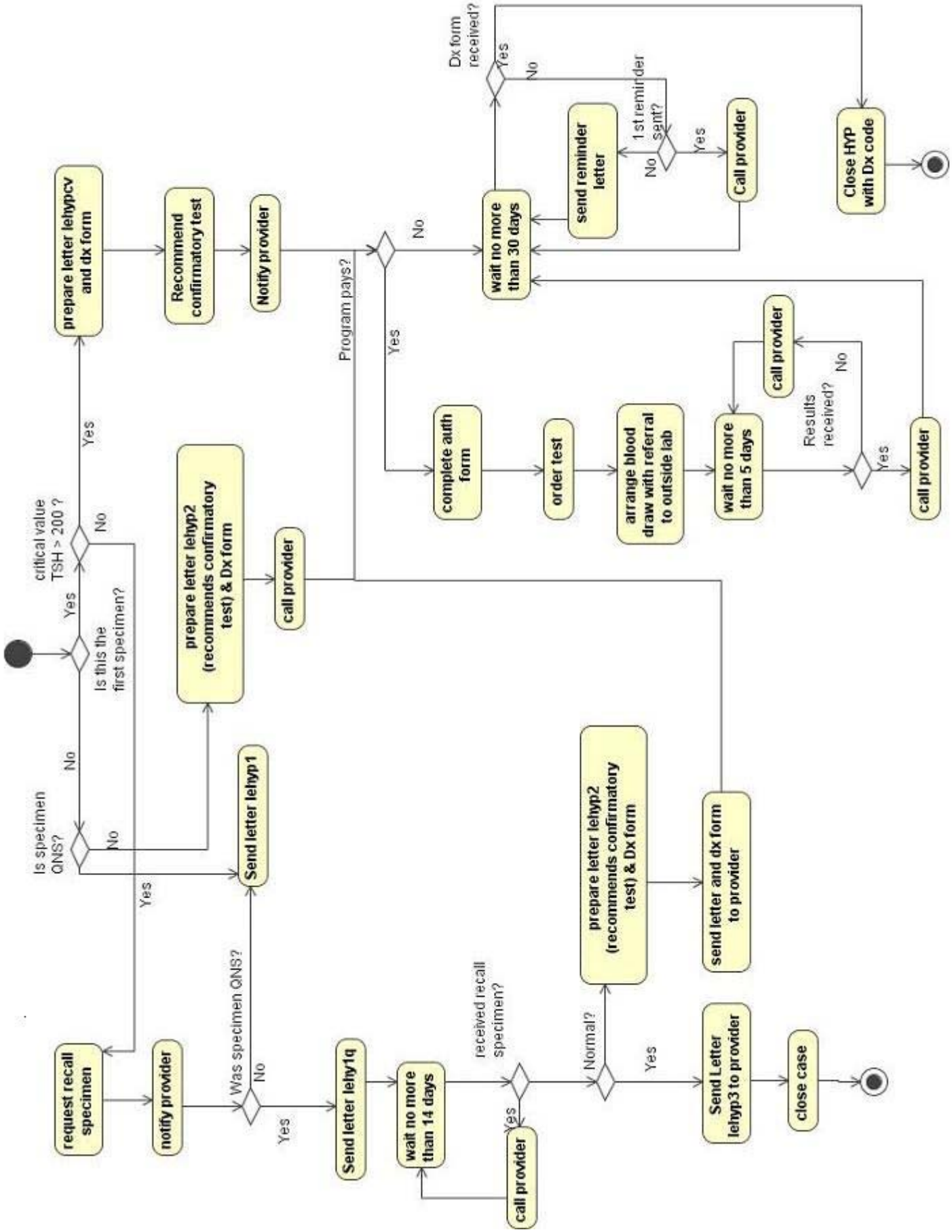


Figure 11. PKU Work Flow Process

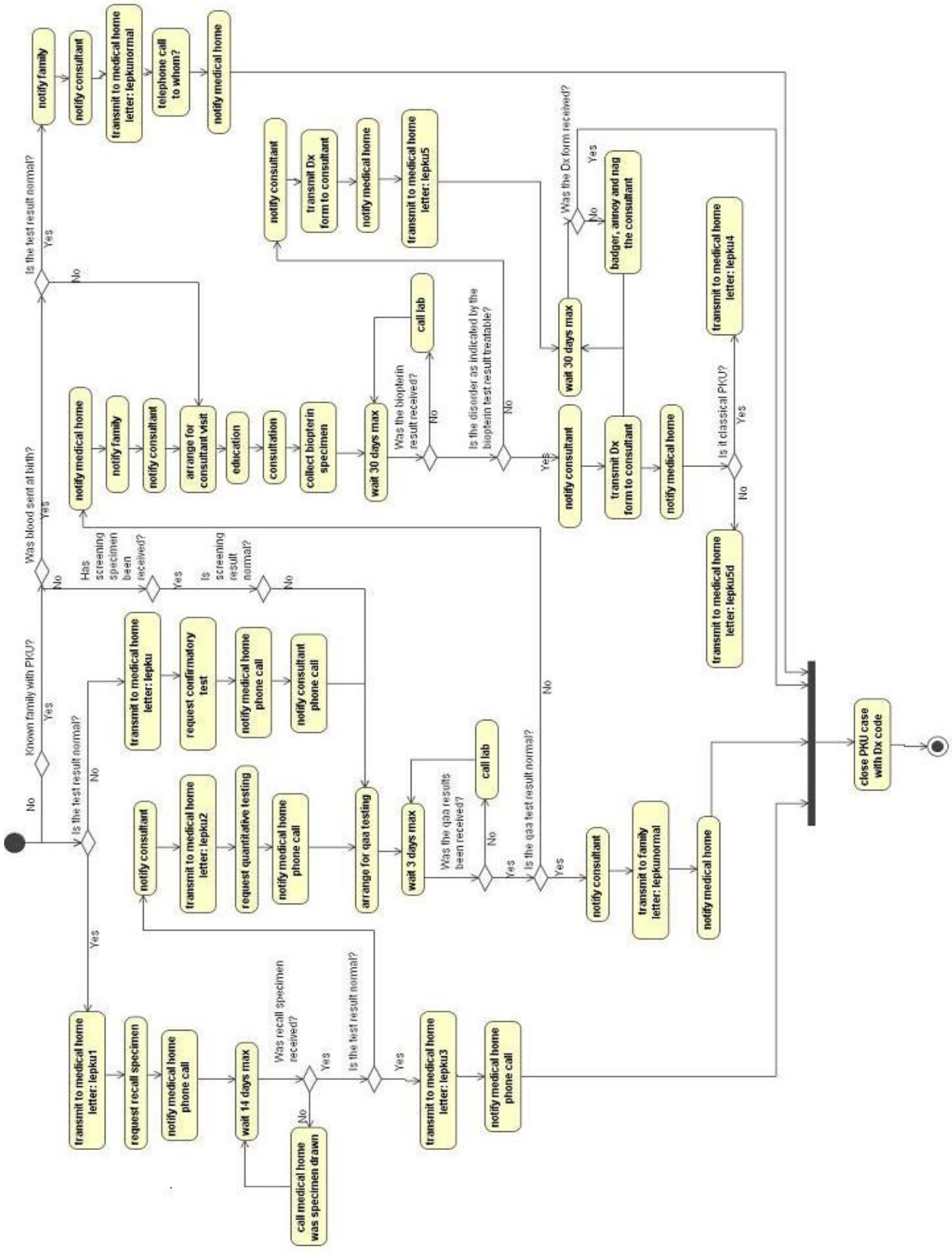


Figure 12. Transfusion Work Flow Process

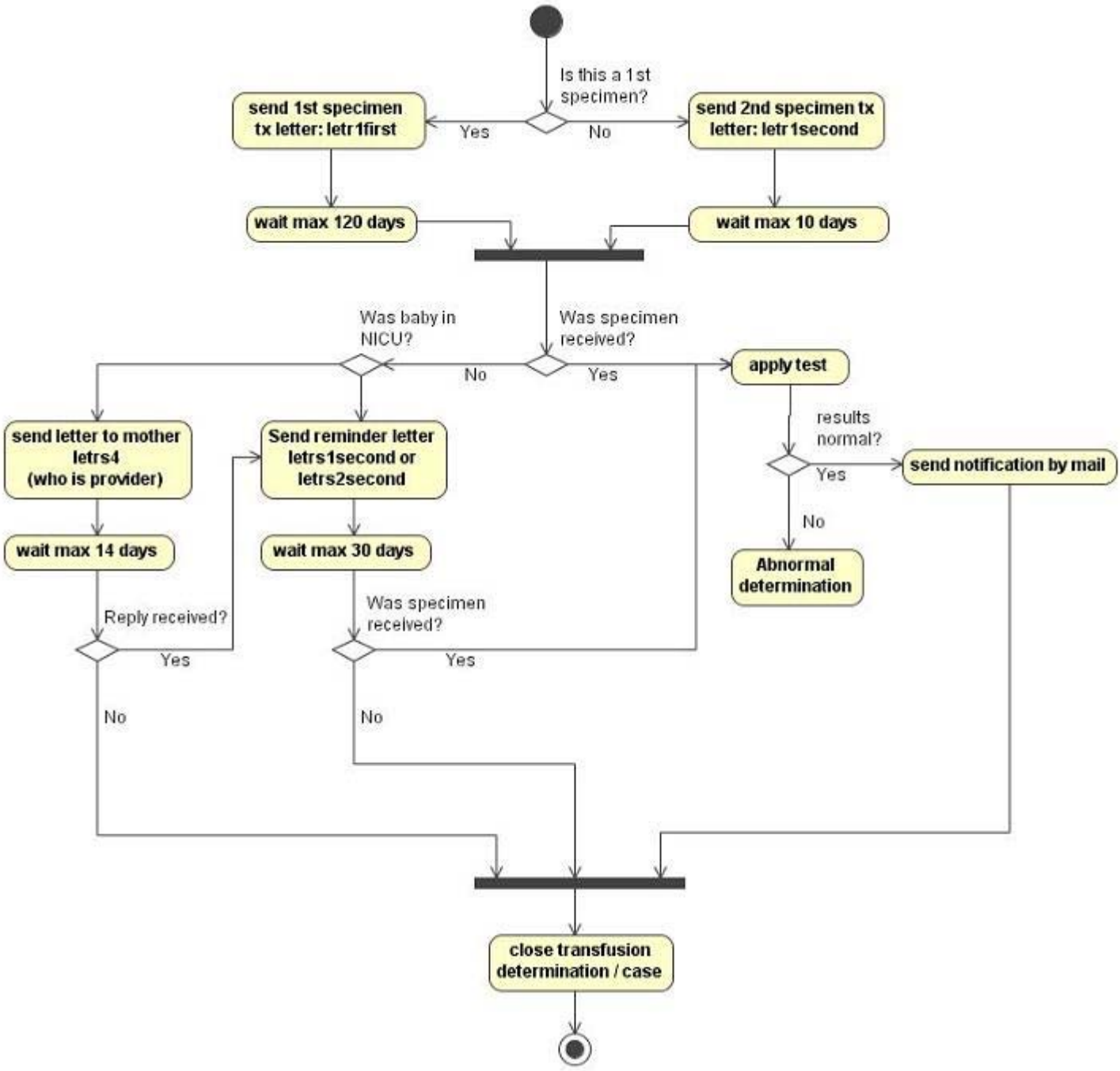
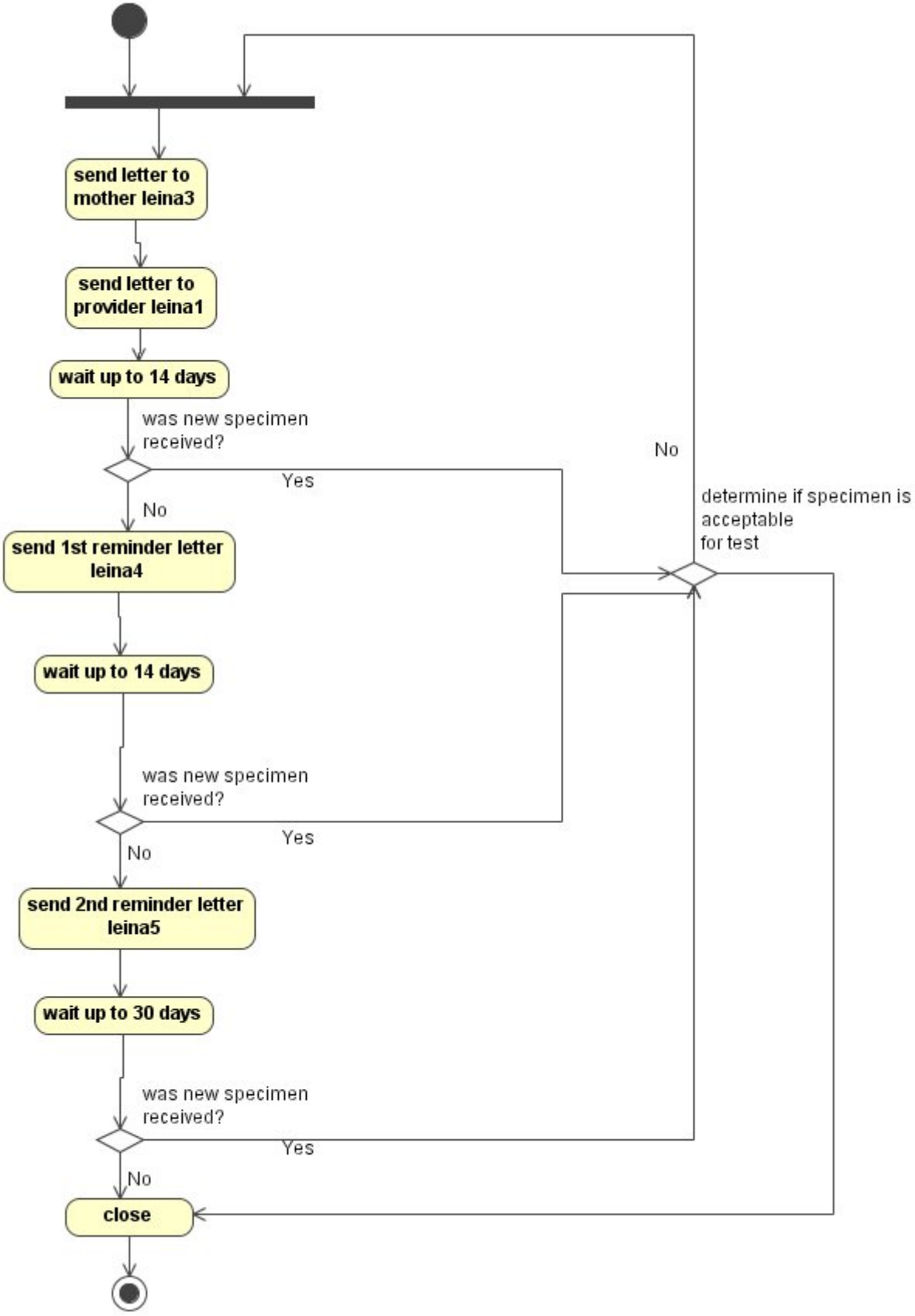


Figure 13. Unsatisfactory Specimen Work Flow Process



NBS - Use Case Analysis - Sample Processing & Kit Management

Chris Peper, UDOH

Brenden Anderle

Revision History
Revision 1.1 2005 Jun 08
Changes from mtg with Chris et. al.

Revision History
Revision 1.2 2005 Jun 13
Final - Revisions added by Program committee.

Revision History
Revision 1.3 2005 Jun 21
Final - minor revisions added by Program committee.

Use-case analysis of the sample procesing and kit management used for Newborn Screening Program. This includes the work-flow processes for the initial intake of kit data, data validation and normal results reporting. Included are interactions with the Newborn Screening Laboratory system.

Table of Contents

1. Overview

The Sample Processing & Kit Management group of Newborn Screening takes the responsibility for the intake of specimen and corresponding data. They also manage the kit inventory and distribution. Specimens are received daily, currently ca 500 per day. These are verified suitable for testing and then processed. Processing involves identifying the specimen, assignment of a bar code (accession number) and entering the demographic data from the card. These general activities and responsibilities are: .

- Intake and suitability control of incoming samples
- Data input accuracy, resolution missing or incorrect data
- Initiate printing and sending of all normal results. (Abnormal go to Case Management)
- Problem solving of specimen data and linkage

- Kit distribution - sell and manage shipping, assigns and track kits sold, inventory control (inventory has limited shelf-life) Providers e.g. hospitals, birthing facilities, midwifes are provided with kits. The distribution of the kits is managed by Sample Processing & Kit Management personnel.

- Customer interface for kit distribution issues

Terminology:

CLIA	Clinical Lab Information Act
kit	Contains first and second demographic & specimen collection card, a parent education brochure, and a postage-paid return envelope.
collection card	currently comprised of 3 sections:

1. In-house blood specimen spots (5) for internal testing (except diet monitoring)
2. Third-party blood specimen spots (2) for external testing
3. Demographics, provider and specimen data

   Included is patient demographic data, provider data, specimen data type (first, second, recall).

2. Enter a First Screen Card

Actors: Data Input, Lab Technician

Pre-condition:

Post-condition: Kit has been accepted for testing, bar code scanned, accession number assigned, data entered.

Primary Scenario:

1. Lab Technician visually inspects blood sample spots for a minimum of 5, verifies that the card has been received before expiration date.
2. Sample sections (2 sets of blood spots) are separated from data section and forwarded for third-party testing.
3. An accession number is assigned as a bar code with human readable characters to both the demographic card and the in-house specimen card.
4. Customer's inventory is updated from specimen kit #.

   See "*Maintain Kit Inventory*" use case below.
5. Card data is entered, all fields are required. Frequently card data is incomplete.

   Specimen Fields are:

   - Accession Number
   - Date Collected
   - Kit Number
   - Date Received
   - Specimen Type (user pick list)
   - Unsat

- Recall
- Reason For rejection (user pick list)

Patient Fields are:

- Baby's Last Name
- Baby's First Name
- Baby's Sex (pick list)
- Baby's Birth Date
- Baby's Weight
- Baby's Place of Birth (pick list)
  - Hospital
  - Home
  - Birthing Center
  - Other
- Hospital / Submitter (pick list)
- Baby's Chart Number

checked fields:

- Multiple Birth
- Home birth
- Adoption
- Breast
- Bottle
- Premature/Sick
- Transfusion

  Transfusion Date

Mother fields:

- Mother's Last Name
- Mother's First Name
- Mother's Maiden Name
- Mother's Address
- Mother's City, State, Zip
- Mother's Phone Number

- Mother's Birth Date

Provider fields:

- Physician ID (pick list)
- Dr's Last Name (pick list)
- Dr's Phone Number (pick list)

6. Card data is dual entered

   For data integrity, data is entered again by a second Data Input user to selected fields:

   Patient Fields are:

   - Baby's Last Name
   - Baby's First Name
   - Baby's Sex (pick list)
   - Baby's Birth Date
   - Baby's Weight
   - Baby's Place of Birth (pick list)
     - Hospital
     - Home
     - Birthing Center
     - Other
   - Hospital / Submitter (pick list)
   - Baby's Chart Number

   checked fields:

   - Multiple Birth
   - Home birth
   - Adoption
   - Breast
   - Bottle
   - Premature/Sick
   - Transfusion

     Transfusion Date

   Mother fields:

   - Mother's Last Name
   - Mother's First Name

- Mother's Maiden Name
- Mother's Address
- Mother's City, State, Zip
- Mother's Phone Number
- Mother's Birth Date

Provider fields:

- Physician ID (pick list)
- Dr's Last Name (pick list)
- Dr's Phone Number (pick list)

7. Samples are sent to Newborn Screening Laboratory for testing.

3. Enter a Second Screen Card

Actors: Data Input, Lab Technician

Pre-condition: First screening card has been processed

Post-condition: Second screening data will be updated if needed

Primary Scenario:

1. See "Enter a First Screen Card" use-case.
2. A separate data record is created for the second screening

   Data is entered or modified using information from the second screening card.

   Data will be entered again.
3. Fields updated from first screening:

   Specimen Fields are:

   - Accession Number
   - Date Collected

   Baby Fields are:

   - Baby's Last Name
   - Baby's First Name
   - Baby's Sex (pick list)
   - Baby's Weight
   - Baby's Chart Number (used by physician)

   Mother Fields

   - Mother's Last Name

- Mother's Maiden Name
- Mother's First Name
- Mother's Address
- Mother's City, State, Zip
- Mother's Phone Number
- Mother's Birth Date

Provider fields:

- Physician ID (pick list)
- Dr's Last Name (pick list)
- Dr's Phone Number (pick list)

4. All modifications are tracked by the audit system

   The following fields are used to track changes:

   - created-by user ID
   - creation date
   - modified-by user ID
   - modification date

4. View Audit Trail

Actors: Sample Receiving Supervisor

Pre-condition: Specimen data has been entered for a patient

Post-condition:

Primary Scenario:

This is a data quality step, to allow the Supervisor to review the entered data for a patient.

1. Supervisor may select patient by kit ID, accession number, patient name or date
2. The data for the selected specimen is displayed, along with all of the audit history records.
3. Supervisor may inspect the differences between records, or the historical changes as tracked by the audit history.

5. Publishing Normal Results

Actors: Sample Receiving Supervisor, Submitter

Pre-condition: Specimen has been received, processed and tested.

Post-condition: Results are transmitted to Submitter.

Primary Scenario:

The usual process flow is that the "normal" results are automatically reported. Currently this is accomplished by generating a report to be mailed, faxed, or emailed.

1. Results are entered onto a queue.
2. Results are transmitted to submitter by preferred method (FAX, mail, email)
3. Any results not able to be transmitted are reported in an exception report.

Alternative *Scenario*:

This is a manual process used for exceptions to automatic to view and create a report of the "normal" result.

1. Supervisor selects sample by accession number, patient or other criteria
2. Normal test results are displayed if available
3. Supervisor may transmit results to Submitter

   User selects the transmission method (pick list):

   - FAX
   - Print (mail)
   - Email
4. Results are transmitted to Submitter.

6. Customer Management

Actors: Data Input

Pre-condition:

Post-condition: Customer data is added, changed or marked for activation or deactivation from customer list

Primary Scenario:

Customer is typically a medical provider, physician, hospital or clinic

1. User adds new or selects existing customer from list
2. Fields available:
   - Customer type (pick list)
   - Name
   - Contact Name
   - Code
   - Address 1
   - Address 2
   - City
   - State
   - Zip

- Active flag
- Phone 1

Note

A user-defined number of phone fields should be available, and the descriptive labels should also be user-defined.

- Phone 2
- Phone 3
- FAX
- E-mail
- Notes
- Preferred Delivery Method (pick list)
  - FAX
  - Print (mail)
  - Email

3. Changes are saved.

   For customers marked for deactivation, their status is set to inactive, and they are no longer visible in application except from this use-case.

7. Distribute Kits

Actors: Sample Receiving Supervisor

Pre-condition: Customer exists in (Provider) list

Post-condition: Order is placed, inventory updated.

Primary Scenario:

1. Supervisor selects menu item for Kit Order Fulfillment
2. Customer is selected from list
3. Check customer's stock-on-hand
4. If customer's stock is greater than some defined quantity

   then Notify customer of existing stock and verify the request to place order.

   Otherwise continue with order.
5. A new order is created
6. Order data is entered:

   Order info:

   - Provider (pick list)

- Number of cards ordered (pick list)

  Upon entry, the card number range is displayed.

- Date order sent
- Date order requested
- Date order filled

Kit Number Format: select one

- 123M456
- M123456

Method of Payment: select one

- Purchase order
- Telephone order
- Cash

  Receipt number

Type of Card: select one

- Routine
- Diet Monitoring
- Miscellaneous

7. Order is saved.
8. Order is filled
9. Order is sent to shipping for delivery.

Alternative Scenario:

If an order already exists and has not been shipped, the Sample Processing Supervisor is presented with a menu item that allows the order to be edited.

1. Supervisor selects menu item for Edit Kit Order Fulfillment
2. Customer is selected from list
3. List of orders for selected customer is displayed
4. Supervisor selects order to edit.
5. Detail for selected order is displayed.
6. Order data is edited:

   Order info:

   - Provider (pick list)
   - Number of cards ordered (pick list)

Upon entry, the card number range is displayed.

- Date order sent
- Date order requested
- Date order filled

Kit Number Format: select one

- 123M456
- M123456

Method of Payment: select one

- Purchase order
- Telephone order
- Cash

Receipt number

Type of Card: select one

- Routine
- Diet Monitoring
- Miscellaneous

7. Order is saved.
8. Order is filled
9. Order is sent to shipping for delivery.

8. Generate Reports

Actors: Sample Receiving Supervisor

Pre-condition:

Post-condition:

Primary Scenario:

Various reports are needed in the management of sample receiving. The following are the currently identified reports, but others may defined later:

ID	Report
1	Kits not Linked
2	Dual Entry Not Done
3	Invalid Dates
4	Failed Faxing
5	Invalid Birth dates
6	Linked Kits
7	Requester File

ID	Report
8	Collection Kit Inventory
9	Ability to Generate Saved and User-defined Queries - see this use-case for list of defined queries
10	Normal Test Result
11	First Specimen, 2nd Specimen
12	Reprint 1st, 2nd

1. User selects report from menu
2. User may be prompted to enter report parameters
3. User generates report
4. User may print, fax or email report
5. User closes report module.

9. Generate Saved and User-defined Queries

Actors: Sample Receiving Supervisor

Pre-condition:

Post-condition:

Primary Scenario:

1. User selects query function
2. User selects query to run elects to create new query
3. If user selects existing query, user is prompted from query parameters.

   Sample Processing - currently defined queries:

   - Waiting for 2nd Entry
   - Waiting for results
   - Find Baby
   - 1st, completed to mailed
   - 2nd, completed to mailed
   - Reprint 1st mailer
   - Reprint 2nd mailer
4. Query runs a results are displayed.
5. If user selects a new query, user is prompted for a new name
6. User creates the query, and any parameters it requires.
7. User is allowed to select the fields and layout for the query
8. Query is saved. Proceed to step 3.

10. Edit Test Request

Actors: Sample Receiving Supervisor, NBS Lab Manager, NBS Lab Screening Supervisor

Pre-condition: Specimen received and data input.

Post-condition: Ordered tests have been changed

Primary Scenario:

1. User selects specimen
2. Current orders tests are selected
3. Test are displayed
4. User may select or deselects tests.
5. User may save or cancel changes.

11. Link / Unlink by Specimen

Actors: Sample Receiving Supervisor

Pre-condition:

Post-condition:

Primary Scenario:

1. Generate the `"Specimen Not Linked"` query
2. Select a kit number or accession number
3. select the link / unlink function
4. display all kits with same kit number
5. user selects kits that are not linked
6. Data must be validated in the linked kits before linking is allowed
7. If the user decides by inspection that the kits should be linked then

   Link kits
8. Save changes
9. Linked kits are displayed as linked (same background color)

Primary Scenario:

Same as Primary Scenario except that kits can be selected to be unlinked

1. see Primary Scenario
2. user selects kits that are linked
3. Data must be validated in the linked kits before unlinking is allowed
4. If the user decides by inspection that the kits should be unlinked then

Unlink kits

5. Save changes
6. Unlinked kits are displayed as unlinked (differ in background color from linked kits)

12. Maintain Kit Inventory

Actors: Sample Receiving Supervisor

Pre-condition:

Post-condition:

Primary Scenario:

1. User selects Kit maintenance screen
2. User may select inventory history for listing of all inventory, where and to whom it was distributed.
3. User selects current inventory
4. User selects Receipt of Stock function
5. Received stock in put into inventory
   - Kit # start
   - Kit # end
   - Expiration date of kits
   - Contact info is verified
6. Changes are saved
7. User able to edit inventory
8. The application and NBS Laboratory system are updated to show that the kit# are valid for receipt, data entry and testing.
9. Inventory is also tracked at customer site

   When a specimen is received, the kit # is recorded by application.

   This allows are report to be created for the customer to notify them of the stock they have used and for new stock orders.

NBS - Use Case Analysis - Laboratory - Test Analysis & Results

Norm K Brown, UDOH

Robyn Weaver, UDOH

Brenden Anderle

Revision History
Revision 1.0 2005 Jun 03 Initial

Revision History
Revision 1.1 2005 Jun 08 Included Norm's revisions.

Revision History
Revision 1.2 2005 Jun 13
Final - Revisions added by Program committee.

Revision History
Revision 1.3 2005 Jun 21
Final - minor revisions added by Program committee.

Use-case analysis of the clinical laboratory processes used for Newborn Screening Program. This includes the work-flow processes for the analysis of screening test results and their publication.

Table of Contents

1. Overview

UPHL - Newborn Screening currently does 5 tests (T4, TSH, GALT, PKU, Hb) and will be expanding to 6 tests (T4, TSH, GALT, CAH, BTTD, Hb) done internally with an additional **30** tests done by 3rd-party out-sourced labs.

Note

The current PE system will be retained as the legacy system. It includes the data reduction and analysis package (Multicalc/Assay Viewer). The use-cases described below are included for completeness and to show interactions with the rest of the application.

The general requirements for the screening test results review are as outlined here:

2. Review Screening Test Results

Actors: Screening Supervisor

Pre-condition:

Post-condition:

Primary Scenario:

1. Select a plate
2. Display the test standards, controls and raw patient test results.
3. Check the worksheet for results, examine raw data values
4. Analyze Standard curve using various correlation methods

   Do correction for statistical outliers, or adjust the standards
5. Determine status of controls
6. Analyze and mark patient wells to be retested.

3. Verify Screening Test Results

Actors: Screening Supervisor, Lab Manager

Pre-condition:

Post-condition:

Primary Scenario:

1. Release results
2. Lab Manager verifies the results see "*Validate Screening Test Results*" case.
3. If results are valid then analysis is finished.

4. Validate Screening Test Results

Actors: Lab Manager, Screening Supervisor

Pre-condition:

Post-condition:

Primary Scenario:

1. Lab Manager reviews the validated data and curve-fit analysis.
2. Lab Manager makes determination by inspection of any abnormal values
3. Lab Manager validated standards and controls with parameters.
4. If results pass this review, the Lab Manager releases them for publication.
5. Otherwise, the retesting is ordered

   Re-tests are ordered for wells or plates using an used portion of the original specimen.

6. Normal results are released (published) back to Sample Processing for submitter notification.

   Screening Supervisor reviews and verifies abnormal results (reports them to Case Management)

   Case Manager receives abnormal results and new cases with determinations

7. Abnormal results are reviewed.

   Daily abnormal test report is generated.

   Straddle report is generated for averaged tests.

8. Released selected abnormal results to Case Management for follow up.

5. Handles Exception Cases

Actors: Screening Supervisor

Pre-condition:

Post-condition:

Primary Scenario:

Screening Supervisor attempts to manage exceptions to the normal testing process. The types of exceptions are listed here:

1. Unsats
2. Recall testing
3. Testing not done
4. Testing done but not reported

The process for handling the exceptions is described here:

1. For Unsat

   Verify that the reason stated by sample processing is accurate.

   Verify that ordered tests are canceled

2. Reviews outstanding tests and verifies that tests will be run in timely fashion.

   Validates that any outstanding tests that can be run are scheduled.

6. Create Reports of Screening Test Results

Actors: Lab Manager, Screening Supervisor

Pre-condition:

Post-condition:

Primary Scenario:

This provides the Lab Manager or Screening Supervisor the reports of the tests to be repeated or confirmed

1. User reports on samples needing confirmation or repeat testing

7. Create Reports of Abnormal Results

Actors: Lab Manager, Screening Supervisor

Pre-condition:

Post-condition:

Primary Scenario:

1. User reports on abnormal

   Report should detail tests where 2 values straddle the cut off value, and should flag for retest.

2. All abnormal results should be reported on a daily basis.

   Print abnormal results.

8. Order new Testing Reagents

Actors: Lab Manager, Screening Supervisor

Pre-condition:

Post-condition:

Primary Scenario:

1. If Inventory Management is available from a vendor, then it would be useful. Material management is a low priority feature.

NBS - Use Case Analysis - Case Managment & Patient Care

Fay Keune, UDOH

Brenden Anderle

Revision History

Revision 1.1 2005 Jun 03

Added Fay's review and edits.

Revision 1.2 2005 Jun 08

Added Fay's review and edits, and the Query Use-case.

Use-case analysis of the case management processes used for Newborn Screening Program. This includes the work-flow processes for the reporting of abnormal screening test results and the subsequent follow-up. Also included are interactions with the Case Management system.

Table of Contents

1. Overview

The Case Management group of Newborn Screening takes the responsibility for all abnormal screening results. The Clinical Laboratory reports the abnormal results. The Case Management personnel provide services to patients, their families, and health care providers. These services are described below in detail.

The general processes are:

- Notification of a provider of an abnormal screening test.
- Request the provider obtain a recall specimen from the patient and send it to Sample Receiving.
- Track the request and receipt of the recall specimen
- Order the confirmatory test
- Report the results of the confirmatory test.

2. Notification of a New Case

Actors: Case Manager

Pre-condition: Abnormal test result has been received by the CM system.

Post-condition: Case Manager views in to do worksheet

Primary Scenario:

1. Case Manager views current cases with abnormal results.
2. The new case appears in the list ordered by the disorder being tested.
3. Case Manager can select each disorder type and see the active cases for each.
4. The disorders (name and abbreviation) that require management are:
    - Amino Acids
    - Acylcarnitine
    - BTDD - Biotinidase
    - CAH
    - HYP - Hypothyroidism
    - GALT - Galactoscemia
    - Hb - Hemoglobinopathies
    - Transfusion
5. Selected action is displayed on Case Manager's to-do list as determined by the decision tree for the disorder.

3. View and Search Active Cases

Actors: Case Manager

Pre-condition: At least one active case is available in the CM system.

Post-condition: Set of cases is displayed that match search criteria

Primary Scenario:

1. Case Manager views list of active cases.

   The following columns should be displayed:
2. Case Manager can search the cases by the following criteria:
    - Kit ID Number
    - Baby's Name
    - Sex
    - Date of Birth

- Mother's Name
- Action Needed
- Date action is to be done

3. Case Manager can use a query to quickly locate cases e.g.
   - Search by last name and birth date
   - Search by Kit ID number
4. List of cases is displayed within the search criteria
5. Case Manager can continue to search or select a case.

4. Perform a Task Action

Actors: Case Manager

Pre-condition: A case for an abnormal test result has been created by the CM system, and has been selected.

Post-condition: Action status may change for the current action.

Primary Scenario:

1. Case Manager views the details of the case. Patient demographics (as entered in the Sample Receipt user case) are displayed:

   List of displayed fields:

   - Last Name
   - First Name
   - Middle Initial
   - Date of Birth
   - Sex
   - Address 1, 2
   - City, State, Zip Code
   - Phone
   - County
2. A to-do list of actions is presented to the Case Manager as process steps.

   Selected action is displayed on Case Manager's to-do list as determined by the decision tree for the disorder.

   These are user-defined actions - see Admin - Creation of Decision Trees use-case.
3. Case Manager can select the action to be taken. As each step is performed, the Case Manager enters the status of each step:

   List of action status items

   - Activated

- Completed
- Completed Unsuccessfully (?)
- Canceled?

Case Manager may enter annotations about the selected action, and designate a contact if applicable.

Decisions are displayed by a modal pop up window. The next process step depends on the Case Manager's response to a question.

4. If preceding step was successfully completed, the next step is presented.

   This may be the result of the answer to a question to make a decision.

5. Selected action is displayed on Case Manager's to-do list as determined by the decision tree for the disorder.

Alternative Scenario:

1. User may select a part of the work flow process that is out of sequence with the current task.
2. User is prompted to enter the reason for moving to different part of work flow.
3. New task list is displayed that corresponds to new position in the work flow (decision tree).

5. Create, Update a Provider Contact

Actors: Case Manager

Pre-condition: Active case exists in the CM system.

Post-condition: A contact may be added or updated.

Primary Scenario:

1. Case Manager selects or searches for case to close.
2. Case Manager selects the contact edit function.
3. The list of provider contacts is displayed.
4. Case Manager may add, edit or make inactive a contact, and designate a default responsible provider.

   Existing providers may be assigned from a pick list.

   This is used for notification.

5. Changes are saved or discarded.

6. Change the Status of an Active Case

Actors: Case Manager

Pre-condition: Active case exists in the CM system.

Post-condition: Status for active case has changed to inactive.

Primary Scenario:

1. Case Manager selects or searches for case to make inactive.

2. Case Manager elects to deactivate the case and enters diagnostic code.
3. A prompt is displayed for the status change reason.
4. Case Manager selects reason and optional comment on why case was deactivated.
5. Case status changes to inactive.
6. Inactive case is removed from display in all active lists.

7. Annotate an Inactive Case

Actors: Case Manager

Pre-condition: An inactive case exists in the CM system.

Post-condition: Case has notes added.

Primary Scenario:

1. Case Manager views inactive cases.
2. Case Manager selects or searches for case to annotate.
3. The selected case is displayed with all fields as read-only.

   Exceptions to this are notes and diagnostic code.
4. Case Manager appends case notes to the case.
5. User saves notes.
6. List of inactive cases is displayed.

8. Generate Notification Letter

Actors: Case Manager

Pre-condition:

Post-condition: Letter is generated that may contain case-specific text added by Case Manager.

Primary Scenario:

1. Case Manager Admin selects active case
2. Details of the case are displayed
3. User may elect to enter a section of text that is specific to the patient or case.

   This section will be appended to the end of the body of the current letter.
4. Selects action to print a notification letter

   User may preview letter

   User prints letter to printer
5. List of to-do actions may be updated to display a new action.
6. User closes the display of the case.

9. View and Report the Case History

Actors: Case Manager

Pre-condition:

Post-condition: Case charting and system notes are displayed in selected order.

Primary Scenario:

1. Case Manager selects the Charting and System notes view
2. The case history is displayed for each action taken.

   Field list:

   - Date Created
   - Created By
   - Comment
   - Contact
3. History report can be printed in various orders for audit purposes.

   Sort order:

   - chronological

10. Generate Reports

Actors: Case Manager

Pre-condition:

Post-condition:

Primary Scenario:

1. Report screen is displayed
2. User selects an existing report to run, or creates a new report see use-case: "User Creates Report"
3. User is presented with report parameters with intelligent defaults
4. User enters desired parameters
5. Report is generated.
6. User may preview report in its printable layout
7. User may print report
8. Report screen is displayed

11. Generate Letters

Actors: Case Manager

Pre-condition:

Post-condition: Selected letter is generated with correct data merged into layout fields.

Primary Scenario:

1. Letter screen is displayed
2. User selects an existing letter to run, or creates a new letter see use-case: "User Creates Letter"
3. User is presented with letter parameters with intelligent defaults
4. User enters desired parameters
5. Letter is generated.
6. User may preview letter in its printable layout
7. User may print letter
8. Letter screen is displayed

12. Create Reports

Actors: Case Manager Admin

Pre-condition:

Post-condition: User has created a user-defined query and created a report to display it. User has saved the report under a unique name for future use.

Primary Scenario:

1. Report creation screen is displayed.
2. Case Manager Admin selects an existing report as a template or selects a report template
3. Case Manager Admin saves the new report with a unique name.
4. Case Manager Admin edits the report query by selecting the desired field (how does the user know what table holds the columns?)

13. Create Letters

Actors: Case Manager Admin

Pre-condition: Case Manager Admin is authorized to make changes to letter.

Post-condition: Letter layout and content are changed.

Primary Scenario:

Currently the letters are created and maintained using Crystal Reports. It has been the users' experience that modifying the letters using Crystal Reports requires a great deal of effort to relearn the skills necessary to accomplish this, because of the infrequent nature of the changes.

The most common changes occur to the layout when the UDOH letterhead changes. This can dramatically change the page layout as some times it is a header only, or perhaps a sidebar and header, or header and footer.

The effort using Crystal Reports is excessive based on the users' experience. The need is for a simpler or more intelligent method for changing letter layouts. The problem is compounded when each of the 40+ letters must be manually changed using the current system.

The requirement here is to allow the user to create a letter using an industry standard word processor e.g. MS

Word or a report writer that will display the merged fields accurately in the graphical layout view.

Also, most letters are defined in context of a decision tree for a particular disorder. The action that prescribes the generation and transmission of a letter should be allowed to automatically link to a created letter.

1. Letter creation screen is displayed.
2. User selects the template (type of letter) to create from the user-defined types e.g. legal notification, normal results report, etc.
3. New page is displayed with applied template for selected letter type.
4. User saves the new letter using user-defined name.
5. User modifies the new page and may edit the template also.

   This allows changes to the header, footer or margins for all letters based on the modified template.
6. User saves the changes and previews the page.

   This displays the page as it will be printed.
7. User closes the page preview. The letter creation screen is displayed.

14. Create, Edit or Delete Decision Tree And Actions

Actors: Case Manager Admin

Pre-condition: Admin role has been established and has access to the Decision Editor

Post-condition: Case Manager Admin has defined a decision process for a disorder and has saved it. The process may be assigned to a disorder as the list of tasks to be taken to manage the case..

Primary Scenario:

Case Manager Admin:

1. Creates a new decision=tree by selecting a menu item.
   - Application prompts user for name and location to save new decision-tree definition
   - New decision-tree definition is created.
2. Creates the actions and decision-tree using a graphical visual editor.

   The user experience should be similar to MS Visio or MagicDraw. The visual symbols should be industry standard e.g. UML 2.0 Activity diagrams. See the Work flow process diagrams for examples.
3. Is able to insert, move and delete action elements.
4. Can edit existing elements and change the process transition links.

   Process actions can be defined to prompt user to answer questions in order to determine next action. The form of the prompt is defined within the action, and typically should be a modal dialog box with the user-defined prompt. It should allow a type-checked response as a text entry, or use buttons or other selection controls as selected by the Admin.
5. Saves changes.

   Alt: may abandon changes

6. Decision-tree definition is written to persistent store.

   Alt: no changes saved.

Alternative Scenario:

Case Manager Admin:

1. Edits existing decision-tree by selecting a menu item.
   - Application prompts user to select existing definition - grouped by disorder
   - Existing decision-tree definition is displayed in graphical UI.
2. Edits or creates the actions and decision-tree using some sort of graphical visual editor.
3. Is able to insert, move and delete action elements.
4. Can edit existing elements and change the process transition links.

   Process actions can be defined to prompt user to answer questions in order to determine next action. The form of the prompt is defined within the action, and typically should be a modal dialog box with the user-defined prompt. It should allow a type-checked response as a text entry, or use buttons or other selection controls as selected by the Admin.
5. Saves changes.

   Alt: may abandon changes
6. Decision-tree definition is written to persistent store.

15. Generate Saved and User-defined Queries

Actors: Case Manager

Pre-condition:

Post-condition:

Primary Scenario:

1. User selects query function
2. User selects query to run elects to create new query
3. If user selects existing query, user is prompted from query parameters.

   Case Management - currently defined queries:
   - New Diets
   - New 1st Transfused
   - New 2nd Transfused
   - New 1st Recall
   - New 2nd Recall
   - Find Baby
   - New 1st Positives

- New 2nd Positives
- New Unsats

4. Query runs a results are displayed.
5. If user selects a new query, user is prompted for a new name
6. User creates the query, and any parameters it requires.
7. User is allowed to select the fields and layout for the query
8. Query is saved. Proceed to step 3.

16. Create Chart NotesGenerate Saved and User-defined Queries

Actors: Case Manager

Pre-condition: A case must exist.

Post-condition: Chart notes have been added to the selected case.

Primary Scenario:

1. Select case (active or inactive) to annotate.
2. Note may be attached to a task, or ad hoc to the case in general.
3. The note is added to the current case, and includes:
   - User id
   - Date & Timestamp
4. Notes are saved as part chart notes.

NBS - Use Case Analysis - Third Party Data interfaces

Fay Keune, UDOH

Brenden Anderle

Revision History

Revision 1.0	2005 Jun 13 Initial

Use-case analysis of the third party interfaces used to communicate patient data and results between UDOH NBS and external labs. It discusses the use of HL7 messages between NBS and third-party laboratories.

Table of Contents

1. Overview

The highest volume of exchanged data is with ARUP. This will increase as the genetic screenings are brought on-line in 2006 Jan 01. The processes outlined here are the general in that most have not been defined.

The underlying message format will be HL7 v.2.3.1 (Minimum Layer Protocol). The data is encrypted by using a secure connection (VPN).

2. Create "Order to Test Specimen" Message

Actors: Sample Processing, NBS Messenger, 3rd Party Lab

Pre-condition: A specimen has been received at Sample Processing

Post-condition: A test has been ordered from 3rd Party Lab using HL7.

Primary Scenario:

1. Specimen's kit id is scanned and accession number assigned. See *"Enter a First Screen Card"* use-case.

   Minimum data with test order is kit ID number

2. An "Order to Test Specimen" message is created and sent to lab by NBS Messenger

   This will be an HL7 message, with minimum data.

   An acknowledgment will be sent to the NBS system that the message was received.

3. At some time later NBS Messenger sends a second message to 3rd Party Lab containing the demographic data for the ordered test.

   This data is used for interpretation of results.

   - Kit ID number

- Date of collection
- Sex
- Date of Birth
- Weight

4. Wait for test results to be completed.

3. Receipt of "Result of Specimen Test" Message

Actors: NBS Messenger

Pre-condition: A specimen has been tested at a third-party lab

Post-condition: The result of the ordered test has been received from the same third-party lab using HL7.

Primary Scenario:

1. At some time within the contractually mandated time the result of the specimen's test will be received by NBS Messenger from 3rd Party Lab. The message format is HL7.

   This result data is as follows:

   - Kit ID number
   - Date of collection
   - Sex
   - Date of Birth
   - Weight
   - Test and interpretation:
     - Amino Acid results (including PKU)
       - Normal
       - Abnormal

         Interpretation and narrative description
     - Acylcarnitine results
       - Normal
       - Abnormal

         Interpretation and narrative description

2. NBS Messenger sends acknowledgment of receipt of message to 3rd Party Lab.
3. NBS Messenger loads result information into application and notifies NBS Laboratory that result is available.
4. Data is validated and released along with results of other tests (see `NBS - Use Case Analysis - Laboratory - Test Analysis & Results` *Validate Screening Test Results)*

- If normal - results are enqueued to Sample Processing for release of results
- If abnormal - results are enqueued to Case Management with determinations